EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO ALL WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

EXPERT REPORT OF DR. VLADIMIR IAKOVLEV

I. BACKGROUND

I am an anatomical pathologist and director of Cytopathology at the Department of Laboratory Medicine, St. Michael's Hospital, Toronto, Canada. I hold an appointment at the Department of Laboratory Medicine and Pathobiology, University of Toronto. My professional activities include diagnostic examination of specimens surgically removed from human patients. These are larger excisions, smaller biopsies and cellular aspirations or smears. The organs and sites include genitourinary organs, gastrointestinal, head & neck, pulmonary, soft tissue and bone. My annual practice volume amounts to 3000-5000 cases. As a clinical physician, I provide clinical consultations to physicians at St. Michael's Hospital, which requires me to examine pathology specimens, review clinical information relating to the patient, and reach conclusions about the cause of a patient's injuries or illnesses. As an academic physician, I pursue research endeavors and teach medical students and residents. My academic activities also include tumor boards and teaching at CME workshops. I am also knowledgeable in the areas of chemistry, hematology, microbiology, serology, immunology and other special laboratory studies as they relate to my practice of pathology.

My pathology training was completed at the University of Manitoba Anatomical Pathology residency program, Canada. I hold medical licenses in the province of Ontario, Canada and in the State of Michigan, USA. As a pathologist with a subspecialty in anatomical pathology, I am a fellow of the Royal College of Physicians of Canada and a diplomate of the American Board of Pathology. For research training, I completed the Molecular Oncologic Fellowship Program at the Ontario

Cancer Institute, Toronto, Canada. A more complete description of my professional qualifications is set forth in my *Curriculum* Vitae, attached hereto. My research career started with a focus on the assessment of histological structures and biomarkers in tissues. Specifically, I became interested in accuracy of measurements, 3-dimensional distributions and tissue heterogeneity.

In 2012, I was approached by Dr. R. Bendavid, who is a recognized authority and an author of several books and numerous publications in hernia repair. He introduced me to the problems of mesh hernia repair, which, in comparison with non-mesh repair introduced unique complications of the mesh: chronic pain, migration and chronic infection. However the exact mechanism of these complications have not been fully studied. Previous studies and manufacturers' testing have been concentrated on experimental modelling in animals and controlled testing in a laboratory environment. A smaller number of research publications showed some pathological mechanisms in samples from patients.

As an anatomical pathologist at St. Michaels, I have reviewed over 250 cases of explanted meshes, including approximately 170 transvaginal mesh specimens. The specimens were from St. Michael's and referring hospitals as well as sent to me as a litigation consultant. All of the pathology that I have reviewed, regardless of the source, has been examined by me in the same manner that I would analyze routine diagnostic specimens according to the standard operating procedures of an accredited diagnostic laboratory.

Data collected from the assessed case have been reported in peer-reviewed journals and presented at scientific meetings as follows:

Full articles:

1. Bendavid R, Lou W, Grischkan D, Koch A, Petersen K, Morrison J, **Iakovlev V**. A mechanism of mesh-related post-herniorrhaphy neuralgia. Hernia. 2015 Nov 23. [Epub ahead of print]
2. V. **V. Iakovlev**, S. A. Guelcher, R. Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from patients. Journal of Biomedical Materials Research part B: Applied Biomaterials 2015; advanced online publication ahead of print.
3. J. G. Blaivas, R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, **V. Iakovlev**. Safety considerations for synthetic sling surgery. Nature Reviews Urology; August 2015, advanced online publication ahead of print.
4. **V. Iakovlev**, E. Carey, J, Steege. Pathology of Explanted Transvaginal Meshes. International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering, 2014, 8(9): 510-13.

5. Bendavid, R., Lou, W., Koch, A., Iakovlev, **V.** Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain. International Journal of Clinical Medicine, 2014, 5:799-810

Abstracts:

1. M Thompson, D R. Ostergard, E Carey, S Guelcher, **V Iakovlev**. Court is in Session: Will Transvaginal Mesh Win or Lose? Interactive Seminar. International Urogynecological Association (IUGA), 40th annual meeting. 2015. Programme.
2. V. **V. Iakovlev**, S. A. Guelcher, R. Bendavid. Histological Features and Clinical Implications of Polypropylene Degradation. Canadian Journal of Surgery. 2015, 58(4 s2):46.
3. **V. Iakovlev**, A. Koch, R. Bendavid. Migration of Polypropylene Mesh in the Development of Late Complications. Canadian Journal of Surgery. 2015, 58(4 s2):46.
4. **V. Iakovlev**, G. Iakovleva, R. Bendavid. Systematic Pathological Assessment of Explanted Hernia Meshes Reveals Important Information of Mesh-body Interactions. Hernia. 2015;19 (S1) P5:04.
5. **V. Iakovlev**, G. Iakovleva, R. Bendavid.
   Explanted Surgical Meshes: What Pathologists are Missing? Modern Pathology. 2015;28(S2):19A:63.
6. **Iakovlev V**, Mekel G, Blaivas J.
   Pathological Findings of Transvaginal Polypropylene Slings explanted for Late Complications: Mesh is Not Inert. International Continence Society (ICS) annual meeting, 2014: 228.
7. R. F. Dunn, S. A. Guelcher, **V. Iakovlev.**
   Failure Analysis of Transvaginal Mesh Products – a Biomaterials Perspective Using Materials Science Fundamentals. 2014 AIChE Annual Meeting: 112f
8. **V. Iakovlev**.
   Explanted Surgical Meshes: What Pathologists and Industry Failed to do for 50 Years. Virchows Archiv 2014, 463(1): 337
9. **V. Iakovlev**, S. Guelcher, R. Bendavid.
   In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35
10. **V. V. Iakovlev**, E. T. Carey, G. Iakovleva, J. Steege, R. Bendavid
    Pathological findings associated with pain in transvaginal meshes. The 20th World Congress on Controversies in Obstetrics, Gynecology & Infertility (COGI), 2014.

Lectures and oral presentations:

1. What do we know about meshes in human bodies? Bard Davol European Hernia Symposium 2015. Berlin, Germany.
2. Migration of Polypropylene Mesh in the Development of Late Complications. Canadian Hernia Society meeting, 2015, Quebec city, Canada.
3. Histological Features and Clinical Implications of Polypropylene Degradation. Canadian Hernia Society meeting, 2015, Quebec city, Canada.
4. Court is in Session: Will Transvaginal Mesh Win or Lose? Interactive Seminar. International Urogynecological Association (IUGA), 40th annual meeting. Nice, France
5. Systematic Pathological Assessment of Explanted Hernia Meshes Reveals Important Information of Mesh-body Interactions. 1st World Conference on Abdominal Wall Hernia Surgery. 2015 Milan, Italy.
6. Pathological findings associated with pain in transvaginal meshes. The 20th World Congress on Controversies in Obstetrics, Gynecology & Infertility (COGI), 2014 Paris, France
7. "SIN syndrome" – A New Mechanism for Mesh Inguinodynia. 1st Annual Abdominal Wall Hernia Conference, Canadian Hernia Society, 2014 Toronto, Canada.
8. Pathology of Explanted Transvaginal Meshes. International Conference on Obstetrics and Gynecology. World Academy of Science, Engineering and Technology. 2014, London, UK.
9. SIN syndrome: Pathological Findings in Explanted Mesh Specimens. Canadian Association of General Surgeons meeting (Canadian Surgery Forum), 2014 Vancouver, Canada.
10. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. 26th European Congress of Pathology, 2014, London, UK
11. Pathological findings in explanted surgical meshes. Shouldice Hospital, 2013, Richmond Hill, Canada.

Poster presentations:

1. Explanted Surgical Meshes: What Pathologists Are Missing? United States and Canadian Academy of Pathology (USCAP), annual meeting, 2015. Boston, United States
2. Pathological Findings of Transvaginal Polypropylene Slings. R. Ross research day, St. Michael's Hospital, 2014, Toronto, Canada.
3. Pathological Findings of Transvaginal Polypropylene Slings explanted for Late Complications: Mesh is Not Inert. International Continence Society (ICS) annual meeting, 2014, Rio de Janeiro, Brazil.

4. Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain. Canadian Association of General Surgeons meeting (Canadian Surgery Forum), 2014 Vancouver, Canada.
5. Explanted Surgical Meshes: What Pathologists and Industry Failed to do for 50 Years. 26th European Congress of Pathology, 2014, London, UK

For the opinions and figures in this report, I have relied on my findings in the explant specimens, including those transvaginal mesh devices manufactured by Ethicon. In addition, I have also relied on data available in peer reviewed publications, including my own peer reviewed publications. A short review of the published literature is provided below:

II. LITERATURE REVIEW

Inflammatory reaction

Inflammatory reaction to the mesh is a non-specific reaction to a foreign body, which was initially described in the 1800`s during the time of Langhans and Metchnikoff [293] [347]. Immediately after placement into the body, foreign objects become coated with human proteins before appearance of the inflammatory cells. The inflammatory cells migrate into the tissue from the bloodstream through the action of inflammatory mediators. As in any tissue injury, short-lived neutrophils appear first at the site marking an acute phase. Neutrophils are replaced within days by macrophages, which stay in the area permanently. The phagocyte migration towards the foreign bodies is mainly dependent on the proteins coating the objects. [484] Specifically, fibrinogen has been shown to play a key role. [483] The macrophages either stay single, taking on an epithelioid appearance, or they fuse to form multinucleated giant cells. The fusion occurs in the presence of certain cytokines [340], which is usually seen when a foreign object is too large to be phagocytosed by a single cell. The collections of epithelioid macrophages and giant cells are the hallmark of granulomatous inflammation, which was originally described as a feature of tuberculosis. [293] The macrophages are recruited in an attempt to destroy the foreign object and the cells secrete an array of substances such as bioactive lipids, hydrolytic enzymes, reactive oxygen metabolites, and mediators of fibroblast proliferation. [294] [24] The cells adhere to the surface of the foreign object, similar to osteoclasts resorbing bone, and their main function is degradation of the foreign material. In addition to macrophages, granulomatous reaction includes T- lymphocytes as well as a smaller proportion of B-lymphocytes and plasma

cells. Each mesh filament becomes surrounded by granulomatous inflammation and the entire mesh structure remains chronically inflamed indefinitely or until the mesh is surgically removed. [25] [153] [244] [265] [557] There are three aspects of mesh induced-inflammation which lead to complications for the patient: chronic foreign body inflammation, excessive scarring as a result of chronic stimulation of fibrosis, and polypropylene degradation.

Mesh integration

Mesh integration into the tissue is the result of repair mechanisms. As in any wound repair, these mechanisms aim to restore continuity of the tissues. Mammalian connective tissue does not regenerate except at fetal stages. In adult mammals, regeneration of soft tissue may occur to a limited degree in some animals. [321] [101] [421] [289] Normally, the damaged tissue and void spaces are filled with fibrous tissue, or scar. This fibrous tissue is used by our body as a non-specific universal repair material or filler. If the wound edges are closely approximated, the amount of scar is minimal and is known as "first intention healing". If the defect is larger, it needs to be filled with granulation tissue first – a process known as "second intention repair". [289] In relation to mesh, the body needs to repair the tissue damaged during surgery as well as to fill the spaces within the mesh structure.

After surgery, the void spaces are filled with blood clot. The clot, with its fibrin matrix, is used as a scaffold for cell migration. Neutrophils appear first, followed by macrophages, and then fibroblasts migrating from the viable edges. [289] [421] Blood vessels at the defect edges become a source of new sprouting capillaries formed by the proliferating endothelial cells. The capillaries supply nutrients for fibroblasts to synthesize collagen - the main component of future fibrous tissue. The initial loose collagenous matrix with abundant capillaries forms granulation tissue, which advances into the tissue defects and replaces the original blood clot and debris. In cases of implanted mesh, granulation tissue inhabits the spaces within the mesh structure – pores and interstices between mesh filaments. Over a course of weeks, the amount of deposited collagen grows, while fibroblasts acquire contractile filaments and transform into myofibroblasts. Their contractile function, together with reduction of extracellular fluid and collagen cross-linking, result in wound contraction aiming to minimize the volume of maturing scar. After the mesh is implanted in a body, the scar contracts within and around the mesh causing the fibers in the mesh to move closer to each other as well as to distort the physical

structure of the mesh. This leads to contraction, or shrinking of the composite mesh-scar structure. [263] [330] [162] [557]

Generally, in wound repair, axons of interrupted nerve branches grow to re-innervate their targets. [416] The same process occurs during tissue repair within and around implanted materials. Meshes implanted in either the anterior abdominal wall or transvaginally become innervated. [215] [216] [557] As anywhere in the body an innervated tissue is subject to all regular mechanisms of pain. The complicating factor in the meshes is tissue division into compartments. Each mesh pore or mesh fold is restricted by the mesh fibers. This tissue compartments include ingrown blood vessels and nerve branches. [215 [216] [557]

The next step in the repair process is maturation of the newly generated fibrous tissue. During this stage, collagen becomes more organized, and the density of microvasculature recedes. Initially, deposited collagen type III is replaced by collagen type I, rearranged to be parallel to tension forces, and cross-linked. The repaired area becomes hypocellular scar, which then is slowly remodeled for a year or longer. If there is repeated or continuous damage to the tissue, the process of repair can renew at any stage. Chronic conditions can generate a large amount of scar tissue due to the recurrent or continuous nature of the process.

In cases of foreign bodies implanted in the tissue, the repair process is complicated by the inflammatory reaction, which is a stimulus for fibrosis. The amount of scar tissue becomes dependent on the counterbalancing processes: stimulus due to foreign body and reduction of scar volume by remodeling. In relation to implanted meshes, fibrous tissue fills the spaces within the mesh structure and surrounds the mesh. [265] [273] [56] [215] [216] [557] Then, while the tissue undergoes contraction and remodelling, the stimulus for fibrosis is stronger around the mesh filaments and weaker away from the filaments, in the mesh pores. Some larger pores may include fat or other components of normal connective tissue, while the surrounding filaments are fully encapsulated by the scar. [274] Where the scar spans, or bridges across the pores, it is termed bridging fibrosis. Mesh designs containing pores of several millimeters (lightweight) after accounting for stretching forces (either during implantation or in vivo), have a greater chance to contain normal non-scar connective tissue. [274] [273] However, the mesh designs that are currently used for transvaginal devices, including the Prolift line of products and the TVT line of products, show a continuous scar plate that encases all of the mesh filaments and spans

across nearly all of the pores. [274] [183] It also provides a rigid connection between the composite mesh-scar structure and the surrounding normal tissue.

Polypropylene degradation

For nearly a half century, scientists around the world have studied polypropylene, including Ethicon's Prolene used in TVT product and have consistently found that polypropylene degrades over time after being implanted in the body. [386] [229] [110] [102] [112] [529] [337] [271] [467] [247] [431] [448] [64] [310] [556].

For example, dating back to the 1970s, Liebert *et al.* found that polypropylene will degrade *in vivo* over time if not adequately protected by antioxidants. [310] In 1998, Prolene was compared to another polymer called PVDF in an animal study.[337] The researchers found that explanted Prolene degraded after 1 and 2 years, while PVDF remained intact. Similarly, later studies also found that surgical polypropylene mesh will degrade over time after implantation in the human body.[110][102][529] [556] Environmental stress and oxidative degradation facilitated by macrophages have been found to be the most likely mechanisms to explain *in vivo* degradation of polypropylene. [60] [337] [386] [229] [110] [102] [112] [529] [337] [271] [467] [247] [431] [448] [64] [310] [556].

Recently, degradation of polypropylene was detected using histological and transmission electron microscopy approaches [211] [215] [216] [556]. This was observed using a combination of histological stains in regular and polarized light. Polarized light microscopy has been reliably used for nearly 100 years to describe the characteristics of explanted foreign materials. [470] As demonstrated by Ethicon's internal documents, the histological methods have been used by Ethicon's scientists to determine whether Prolene degrades in vivo. The findings lead Ethicon's scientists to conclude that Prolene degrades forming an outer layer of degraded material and the cracking observed on the surface of Prolene by scanning electron microscopy is altered polypropylene and not proteinaceous material. [156] The main feature of degradation is cracking of the polypropylene surface [386] [229] [110] [102] [112] [529] [556]. Similar process occurs outside of body. [467] [247] [431] As a result, the material loses tensile strength and becomes brittle. Loss of mechanical properties was shown in explanted meshes. [448] Cracking also indicates that there are internal forces acting to shrink and deform the material. In relation to clinical symptoms, degradation needs to be considered as a factor of additional stiffening and late deformations of the mesh, independent of stiffening and deformations related to scar

maturation, ingrown scar contraction, mesh folding/multilayering. An important conclusion should be made that if chemical and physical properties of a material change while it is in the body it should not be used for permanent applications and for anatomical sites from which the devices cannot be safely removed. There should be planned exit strategies for complete and safe device removal and with minimal residual tissue damage.

The literature also includes a much smaller number of publications that question whether polypropylene fibers degrade in vivo. [467] [247] [558] The alternative hypotheses were that the cracking either occurs within a proteinaceous layer (i.e., biologic) or was caused by sample preparation (e.g., drying, formalin or chemical reagents used to clean the explanted material prior to examination). Ethicon's experts have similarly espoused in prior cases that a protein-formaldehyde polymer forms around the mesh fibers while the mesh is being stored in formalin. The hypothesis has not been proven and Ethicon's own scientists made conclusions disproving this hypothesis. The hypothesis is not viable since there are multiple features disproving it: the degradation layer retains premanufactured dye granules and optical properties of polypropylene, is can melt and meld with non-degraded polypropylene, cracking of the mesh fibers can be observed immediately after the mesh is removed from the body, the degradation layer does not form around some other implantable materials (GoreTex, polyester), its thickness correlates with time in the body but with time of storage.[556] Also, testing of polypropylene by multiple manufacturers indicates that it is resistant to formalin, which contradicts the theories that exposure to formalin causes polypropylene to degrade. [555]

Review of Ethicon's internal documents

In addition to my review of the peer-reviewed publications, I have also reviewed internal Ethicon documents and the deposition of an Ethicon scientist, Dr. Thomas Barbolt. Ethicon's internal documents and the testimony of Dr. Barbolt provide further evidence that the Prolene will degrade over time after implantation in the human body.

In 1983, Ethicon's scientists used nearly identical methods used by me to determine whether Prolene degrades *in vivo*, including histological preparations, light microscopy, and polarized light. [156] Like my own studies discussed herein, Ethicon's scientists found that Prolene degrades and cracks after implantation in the human body. Interestingly, just as I found in this and other mesh explants, Ethicon's scientists opined that "the cracked layer appeared blue in gross specimens and blue dye particles were evident in histological sections of the layer. This

would indicate that the layer is dyed Prolene polymer and not an isolated protein coating on the strands."[156] Thus, using nearly the same methods as I use routinely in my practice as a pathologist, including the work I performed in the present cases, Ethicon's scientists concluded not only that the surface of Prolene degrades *in vivo*, but also that proteinaceous material was not a likely cause to explain the surface cracking observed on the explanted Prolene fibers, undermining the hypothesis that the cracked layer observed on explanted Prolene fibers is biological or proteinaceous in nature rather than degraded polypropylene.

Ethicon's scientists continued to study *in vivo* changes of Prolene and their findings were consistent throughout the years. For example, Ethicon conducted a 10-year dog study that began in 1985. During the 10-year dog study, Ethicon's scientists concluded "the PROLENE surface, intact at the two year point, showed signs of degradation at five years."[157] Ethicon's scientists also determined that sample preparation was not what caused the cracking: "it can be said unequivocally that the cracking that was seen in any of the sutures was not introduced by sample preparation, i.e., drying. If cracking was observed on a dry suture in the light microscope or in the SEM, the same cracking was also found on the same suture after it had been in body fluids and then in sterile water, without ever having dried."[157] Moreover, formaldehyde was not used in this dog study, further undermining any claim that the cracking observed on the explanted Prolift and/or TVT devices is caused by a formaldehyde protein polymer.

After seven years, Ethicon's scientists reached a similar conclusion made years later by Mary *et al.*, that "degradation in PROLENE is still increasing and PVDF, even though a few cracks were found, is still by far the most surface resistant in-house made suture in terms of cracking."[158]

Furthermore, in 1987, Ethicon's scientists conducted a number of studies using human Prolene explants provided by Prof. R. Guidoin and likewise concluded that the Prolene degraded *in vivo*.[132] [159]

I also reviewed the deposition of Ethicon's scientist, Dr. Thomas Barbolt, who testified that the antioxidants used by Ethicon to protect Prolene from degradation can leach out of the fibers into the host tissue. [133] Dr. Barbolt testified that the Prolene used to manufacture both the Prolift products and the TVT products can undergo surface degradation. Dr. Barbolt further testified that Prolene can undergo surface degradation and that it was known by Ethicon before 1992, and that it was falsely stated in the IFU that Prolene is not subject to degradation. [133]

Effect on the tissue

Pain

Scar tissue inhabiting the mesh is not inanimate filler, but living tissue with vasculature, innervation, fluid and acid-base balance, and immune response. [56] [388] [464] [557] The tissue is subject to regular mechanisms of pain, out of which there are two main mechanisms for pain: direct irritation of nerve branches and irritation of receptors they supply.

Direct irritation of nerve branches can occur due to nerve entrapment with scar tissue within or encapsulating the mesh. [56] [216] [266] [274] [351] [509] [557] The nerves can also become distorted while growing through the mesh and can form traumatic neuroma, a tumor like nerve enlargements known for its painful nature. [274] [351] [509] The entrapped and distorted nerves are also at risk for additional pulling, compression and distortion forces due to the earlier described mesh-scar contraction and non-physiological attachments to the surrounding mobile tissues. Nerve involvement has been reported to exceed 60% for meshes excised for reasons of pain. [274] [56]

In regards to irritation of pain and other receptors the risks are due to specific factors: persistent chronic inflammation, fluid balance, blood supply, physical interlock within the mesh, and non-physiological attachments to mobile tissues. During our lifetime, we all experience the effect of inflammatory mediators causing hypersensitivity of pain and other (touch etc.) receptor. This leads to pain to touch or with movement, and if a stimulus is sufficiently high, it can cause pain at rest. [249] As discussed earlier, polypropylene meshes are invariably associated with a chronic inflammatory response, which creates the background capable to lower the pain sensitivity threshold.

Another specific factor within the mesh-scar complex is its compartmentalizing nature and attachments to the surrounding tissues. The ingrown tissue is in a vulnerable position for physical compression and distortion within the compartments of mesh pores and folds. The risk of compression can occur as a result of external forces, as well as from increased interstitial fluid pressure within the compartments. Externally, scar connection to the surrounding tissue leads to distortion and pulling during movements. Additionally, mesh shrinking during scar contraction leads to static tension within and between the attached tissues.

It is important to note that in hernia surgery, where chronic pain after mesh repair is a growing problem prophylactic neurectomy is offered as a method to reduce incidence of pain after mesh repair. [227]

Mesh migration

Mesh migration through the tissues and into the adjacent organs has been described in hernia applications, where two types of migration were suggested: primary migration of unsecured mesh towards least tissue resistance, and secondary migration through transanatomical planes. The latter is facilitated by tissue forces acting to displace mesh and by the environment making the movement possible: specifically tissue resorption facilitated by inflammation and the ability of tissue to remodel. [192] [10] In the case of transvaginal devices, the migration occurs into or through the urethral or bladder wall, [130] [65] [299] [76] which is a secondary type of migration. Mesh migration is also one of the mechanisms for mesh erosion through vaginal mucosa.

Deformation (folding, curling)

A related phenomenon is mesh deformation, where a part of mesh moves from its original or intended position. Comparatively, during the search for the "ideal mesh", knitted meshes were found to be more prone to fold or curl at the edges. [152] Similar to migration, deformation can be primary due to intra-/perioperative folding and edge curling of an unsecured mesh, or secondary occurring after tissue ingrowth. Secondary wrinkling, folding, curling or "roping" is attributed in large part to forces placed on the mesh both during implantation and in vivo as well as mesh-scar contraction. [263] [354] [389] [545] [546] [553] [557]

Contraction/Shrinkage

For many years, it has been widely reported in the scientific literature that polypropylene surgical meshes undergo what has been called "mesh contraction" or "mesh shrinkage" after implantation in the body's tissues. [274] [266] [547] [548] [549] [550] [551] [552] The mesh fibers themselves do not shrink; rather, it is the wound or damaged tissue surrounding the implant which undergoes normal wound contraction that causes a reduction in the surface area due to retraction of the fibrotic scar tissue in and around the mesh implant. All polypropylene meshes will contract in variable amounts, reportedly between 20 -50 % or more of the original surface area. The contraction tightens the mesh devices and leads to tissue and organ damage.

One of the clinical manifestations of mesh tightening by contraction is the mechanism for urinary outflow obstruction.

Mesh stiffening

Ethicon's IFU claims that the mesh will remain soft and pliable after implantation into the women's pelvis. Contrary to this claim, however, as a result of the excessive scaring around the mesh, as well as the *in vivo* degradation of the mesh the mesh devices become harder and more rigid after implantation than pristine devices. [523] [223] [263] [261] [227] Elasticity of pristine mesh is due to movements and bending of the mesh fibers. After implantation the mesh acts more like stiff rebar within the scar tissue while the ingrown scar blocks movement of the mesh fibers. Thus both the mesh and the scar act to stiffen and harden the composite mesh-scar structure. The resultant mesh-scar plate is stiffer and harder than the surrounding normal soft and elastic tissue. While the scar matures to stable firmness within a year, degradation of polypropylene with resultant stiffening of the mesh is progressive over the years. Therefore, the initial stiffness due to mesh folding/curling and scarring is further aggravated by material degradation over the following years in the body.

III. OPINIONS

I hold all opinions set forth in this expert report to a reasonable degree of medical and scientific certainty. The basis for each of my opinions is my education; my training; my professional experience as a pathologist; and the published, peer-reviewed medical and scientific literature, including my own peer reviewed literature. Each of the opinions and figures identified below are based on my review of the Ethicon's transvaginal mesh specimens the specimens that have been reviewed and identified in published peer reviewed journals.

Summary opinion

The mesh acts as a foreign object and the body attempts to degrade and isolate the mesh. The mesh itself, as a foreign object, and the body reaction to the mesh damage the tissues in a critical anatomical location. This damage occurs in all patients, however to a variable degree. The manifestations range from subclinical to fully developed complications triggering mesh excision.

The components of the above opinion are as follows:

1. **Critical anatomical location.**

Synthetic implantable materials act as foreign bodies which can cause complications for all implantable devices, but this drawback becomes especially critical in the transvaginal locations due to the following factors:

- There are no sharply separated parallel anatomical planes, but rather several round mobile organs in a narrow pelvic space. The mesh cannot be placed parallel to the organs and is not separated from them by anatomical structures.
- There are several organs that need to expand and contract for their function. The mesh cannot contract or expand, moreover, together with encapsulating scar it provides non-physiological connections to the mobile organs.
- The devices are designed to be implanted superficially under sensitive mucosa and can easily become eroded through the mucosa, either due to mesh migration or mucosal breakdown.
- The devices are designed to correct anatomical position of the organs, therefore are designed to press against the organs. This pressure can force the mesh to migrate into the organs.
- Placement through contaminated filed and mesh exposure provide routes for infection.
- The mesh devices cross paths of normal innervation and vascular supply to the mucosa, the bladder and the rectum. After implantation the innervation and vascular supply need to be restored either through or around the mesh.
- The arms and slings are designed to be pulled through the pelvic deep soft tissue and skin, therefore they cross muscles and innervation network of the soft tissues and skin.

2. **Foreign body type inflammation**. The mesh causes a foreign body response. This reaction is aimed to degrade the foreign object and persists until the inciting agent is either removed (expelled) or resorbed (degraded). The reaction is observable microscopically. Images in Figure set 1 are representative of the foreign body response to the Ethicon transvaginal mesh.
3. **Scar ingrowth and encapsulation.** After implantation, the empty spaces within the mesh have no pre-existent tissue and become filled by fibrous tissue, or scar. The surrounding normal tissue can be pulled into the spaces focally during scar contraction and

maturation, but the filaments are always surrounded by fibrous scar. While scar formation is a physiological part of healing process, it is not a functional, but a non-specific replacement tissue. Scar formation is further exacerbated and amplified by the inflammatory stimulus described above. These processes result in a formation of a mesh-scar plate. The mesh and the scar tissue form a composite structure where both, the mesh and the scar reinforce each other and the composite structure is stiffer than a new mesh or scar tissue without the mesh within. Images in the Figure set 2 are representative of scar plate formation in a woman's pelvis as a result of the implantation of the Ethicon transvaginal mesh devices.

4. **Mesh contraction.** As any scar tissue, the scar within and around the mesh contracts during maturation. This leads to contraction of the mesh-scar composite structure. Contraction of the mesh results in its deformation and tightening. Overtightened devices can compress organs and tissues. Tightened devises also can form ridged bands under sensitive mucosa.
5. **Mesh-scar innervation.** The scar inhabiting and encapsulating the mesh is innervated where the nerve branches grow around the mesh and through the mesh pores to re-innervate their targets interrupted during surgery as well to innervate the new tissue (neo-innervate). The innervated tissue is exposed to all regular pain mechanisms of direct mechanical irritation of the nerves as well as irritation of the receptors by the inflammatory and physical mechanisms of pain. Since the compartments are fused by fibrous tissue, the 3-dimensional mesh structure becomes fixed and the neurovascular structures become trapped within. By contrast, mature scar tissue after non-mesh surgeries does not show inflammation, does not have compartmentalization of mesh structure, and can remodel with time, therefore does not exhibit the same risk for pain. Images in Figures set 3 are representative of Ethicon transvaginal mesh innervation in the pelvis.
6. **Severe deformation of nerves and formation of neuroma type lesions.** Traumatic neuromas are known to be painful lesions. Similarly, nerves can become damaged by the mesh, either by migration or during contraction. Severly distorted nerves form traumatic neuroma type lesions. Some nerves can show degenerative type lesions. Figure set 3.
7. **Involvement of neural ganglia.** The mesh can also affect neural ganglia indicating that innervation of the internal organs such as urinary bladder and the rectum can also become

affected. Microphotographs of mesh affecting the neural ganglia are shown in Figure set 4.

8. **Innervation of female genital organs.** Furthermore, the female genital area has much higher nerve density compared to the midline anterior abdominal wall and the groin. The scar inhabiting and surrounding the transvaginal meshes has the highest nerve density out of all explanted surgical meshes I have examined as a pathologist. Thus, placement of the vaginal mesh is associated with higher risk for chronic pain than the placement of the mesh for hernia repair, either ventral or in the groin.
9. **Stiff irregular mesh-scar plate under sensitive mucosa.** The hardened and stiffened mesh-scar plate is located under richly innervated and sensitive vaginal mucosa. This relationship puts the mucosa under risk for pain if it becomes compressed against the mesh-scar plate (intercourse, tampon use). Examples of mucosal innervation over the mesh are shown in Figure set 5.
10. **Higher sensitivity for pain due to inflammation.** As discussed earlier, the mesh is invariably associated with a chronic inflammatory response. It is known that inflammatory mediators lower sensitivity threshold of the pain and other receptors. Therefore tissues surrounding the mesh are more sensitive for pain than a scar without inflammation.
11. **Tissue edema.** It is well studied that inflammatory mediators can change vascular permeability and tone which leads to tissue swelling (edema). Edema can be also caused by partial constriction that is sufficient to compress the low-pressure outflow vessels (venules and lymphatics), but not the inflow arteries and arterioles. Thus pain due to swelling is present in cases of inflammation and trauma and the effect is amplified in rigid compartments. A knitted mesh introduces multiple compartments and constriction points as the mesh pores and folds/curls. There are areas with dilated and congested vessels and edematous stroma within the mesh pores and folds. Images in Figure set 6 are representative of these pathological changes in the female pelvis as a result of the Ethicon transvaginal mesh.
12. **Involvement of striated (skeletal) muscle.** In explanted Ethicon transvaginal mesh devices striated muscle has been detected either interpositioned through the mesh structure, connected to the mesh by the scar, or surrounding the mesh on both sides. Figure set 7 shows representative

examples of the presence of striated muscle in explanted mesh devices. In the cases when the muscle is attached to the mesh, muscle contraction can result in pulling of the entire mesh, the scar tissue, and the nerves that have ingrown into the scar. The resultant pain can irritate the muscle and cause a spasm type contraction as it occurs in renal and biliary colics or muscle spasm in the cases of back pain. This can cause a self-propagated pain-spasm reaction.

13. **Involvement of smooth muscle of the vaginal wall, urinary bladder, urethra and rectum.** In explanted transvaginal mesh devices, the smooth muscle of the pelvic organs can become affected by the mesh. Microphotographs in Figure set 8 are representative of the presence of smooth muscle in explanted mesh devices. This can interfere with the muscle contraction and the organ function and can also apply a force to the mesh during muscle contraction. Involvement of the muscle of the bladder and urethra can affect their function and produce sensation during muscle contraction. Connection to the smooth muscle of vaginal wall can interfere with its contraction (intercourse etc.). Mesh migration into the rectal muscle can be felt and interfere on bowel movement.
14. **Vascular thrombosis and obliteration.** Mesh placement is associated with vascular damage, where both the larger vessels and the smaller capillaries can become affected. Tissue affected by insufficient blood supply can undergo necrosis and/or fibrosis (scarring). Ischemia can also be associated with sensation of pain. Examples of vascular damage are shown in Figure set 9.
15. **Mesh folding and curling.** In addition to the mesh pores and interstices, a deforming mesh forms curls and folds that become partially enclosed compartments. These compartments provide a similar mechanism for ingrowth and entrapment of the nerves, vessels and the muscles identified above. Curled and folded mesh is stiffer than a single layer of a flat mesh. A curled/rolled sling tape also has a smaller area for pressure distribution and has a higher chance to cut through the tissues than a flat tape. Irregularly folded larger pelvic organ prolapse devices exercise focal pressure on the tissues at the prominent folds and form ridges and bands. Figure set 10 shows representative images of curling/folding of Ethicon mesh that has been explanted from the female pelvis.
16. **Mesh migration**. The mesh can migrate in the human tissue. The migration is either primary (intra/perioperative migration of unsecured mesh) or secondary (inflammation and tissue remodelling provide path for the mesh to migrate while body forces act to displace the mesh). Its migration causes damage of the tissues on its path: such as mucosa, nerves, vessels, neural ganglia, urethra, bladder and the rectum.
17. **Mucosal erosion**. Mucosal erosion of the mesh is a complication unique for the mesh surgeries. It cannot happen without the use of mesh. There are two main mechanisms for mesh erosion:

mesh migration and the breakdown of the overlying mucosa. Mesh migration is discussed in #15. The mucosal breakdown can have complex mechanisms where infection, vascular supply, tissue mobility, size and depth of the mesh device and other factors can play roles. Images of mucosal erosion are shown in Figure set 11.

18. **Acute inflammation due to mucosal erosion.** Mucosal erosion of the transvaginal Ethicon mesh becomes a chronic open wound and an entry for infectious organisms. This is associated with acute inflammation and formation of granulation tissue. Fragile granulation tissue produces discharge and bleeds easily. Presence of bacterial infection triggers acute inflammatory response which becomes superimposed on the earlier described chronic non-specific and foreign body type inflammation. Examples of superimposed acute inflammation are shown in Figure set 12. This additional inflammation plays role in tissue damage and further stimulus for pain receptors.
19. **Polypropylene degradation.** Microscopic examination of explanted Ethicon mesh confirms what has been reported otherwise in the medical and scientific literature: polypropylene degrades *in vivo*. Examination reveals a polypropylene degradation layer on the outermost layer of the mesh filaments. The layer differs from the non-degraded core by its ability to trap histological dyes in the nanocavities produced in polypropylene due to degradation. At the same time the degraded material retains inclusions (blue granules) and optical properties (birefringence in polarized light) of polypropylene. Figure set 13 shows representative images of the degradation layer in explanted Ethicon transvaginal mesh devices.
20. **Absence of degradation after exposure to formalin and chemicals of tissue processing.** Polypropylene of pristine polypropylene mesh, including Prolene does not degrade due to exposure to formalin. This has been shown in my experiments and texting by several manufacturers. Examples of mesh after exposure to formalin up to 4 month followed by routine tissue processing are shown in Figure set 14.
21. **Gradual growth of the degraded year over the years in the body.** The degraded layer on an implanted polypropylene mesh, including Prolene accumulates gradually over the years in the body. See Figure 15. As a result, the mechanical properties of the mesh fibers change. The degraded layer cracks indicating its brittleness. As in many brittle porous materials brittleness and porosity are not exclusive of each other.
22. **Cracking of degraded layer observed immediately after mesh removal from the body.** The cracked degradation layer can be visible immediately after excision See Figure

16. The claims that the cracked layer is dried biofilm-proteins or formalin-protein polymer are unsubstantiated since cracking can be seen before the proteins could dry or be cross-linked by formalin.

23. **Melting of degraded polypropylene due to surgical cautery.** The degraded layer shows sites of melting occurred during the use of surgical cautery during excision. This finding confirms that the degraded layer was present before the excision surgery and formed in the body. The bark mixes with the non-degraded core while melting which confirms that it is compatible with the core polypropylene. The feature is shown in Figure set 17.

24. **Absence of stainable layer on non-polypropylene implantable polymers**. In cases when polypropylene mesh was secured by non-polypropylene permanent sutures the non-polypropylene materials do not show formation of a stainable outer layer. If the layer was formed by body proteins it would not have a strict preference to one polymer. See Figure set 18.

25. **Correlation with internal Ethicon documents.** Based on the features described in opinions 16-23, review of the body of scientific literature, review of Ethicon's internal documents and internal studies, it is my opinion that Prolene polypropylene used by Ethicon degrades *in vivo*. Figure sets 19.

26. **Degenerative calcifications can form** triggered by the mesh related pathological tissue changes.The calcific deposits are different from degraded polypropylene. In cases were the mesh migrates into the bladder these calcifications can grow to larger bladder stone.

27. **Mesh excision cannot restore pre-existent tissue state.** Mesh placement causes tissue damage, then while in the body the mesh induces scarring, contracts and migrates expanding the zone of tissue damage. An excision either removes the mesh and all surrounding scarred/damaged tissue leaving a larger defect, or partially removes the scar plate leaving a smaller defect but with a larger amount of remaining scar. In either scenario the defect needs to heal through scarring. Additionally, in many cases mesh cannot be removed in its entirety, especially from the transobturator and other difficult to access locations.

I reserve the right to supplement this report if new information becomes available.

Sincerely,

Vladimir Iakovlev, MD, FRCPC, FCAP

DATE: January 29, 2016

FEES

My billing rate is $475/hr.

LISTING OF CASES IN WHICH TESTIMONY HAS BEEN GIVEN IN THE LAST FOUR YEARS

Lisa Marie Fontes, et al. v. American Medical Systems, Inc.; 2:12-CV-02472

Debbie Jilovec, et al., v. American Medical Systems, Inc.; 2:12-CV-05561

Joann Serrano, v. American Medical Systems, Inc.; 2:12-CV-3719

Mary Weiler, et al. v. American Medical Systems, Inc.; 2:12-CV-05836

Carolyn F. Smothers v. Boston Scientific Corp. ; 2:12-cv-08016

Katherine L. Hall v. Boston Scientific Corp. ; 2:12-cv-08186

Julia Wilson v. Boston Scientific Corp. ; 2012-02626

Ronda Orozco, et al., v. Boston Scientific Corp. ; 2012-03068

Maria Cardenas v. Boston Scientific Corp. ; 2012-02912

Diane Albright v. Boston Scientific Corp. ; 2012-00909

Deborah Barba v. Boston Scientific Corp.

FIGURE SETS

All images represent explanted Ethicon transvaginal devices (unless indicated otherwise)

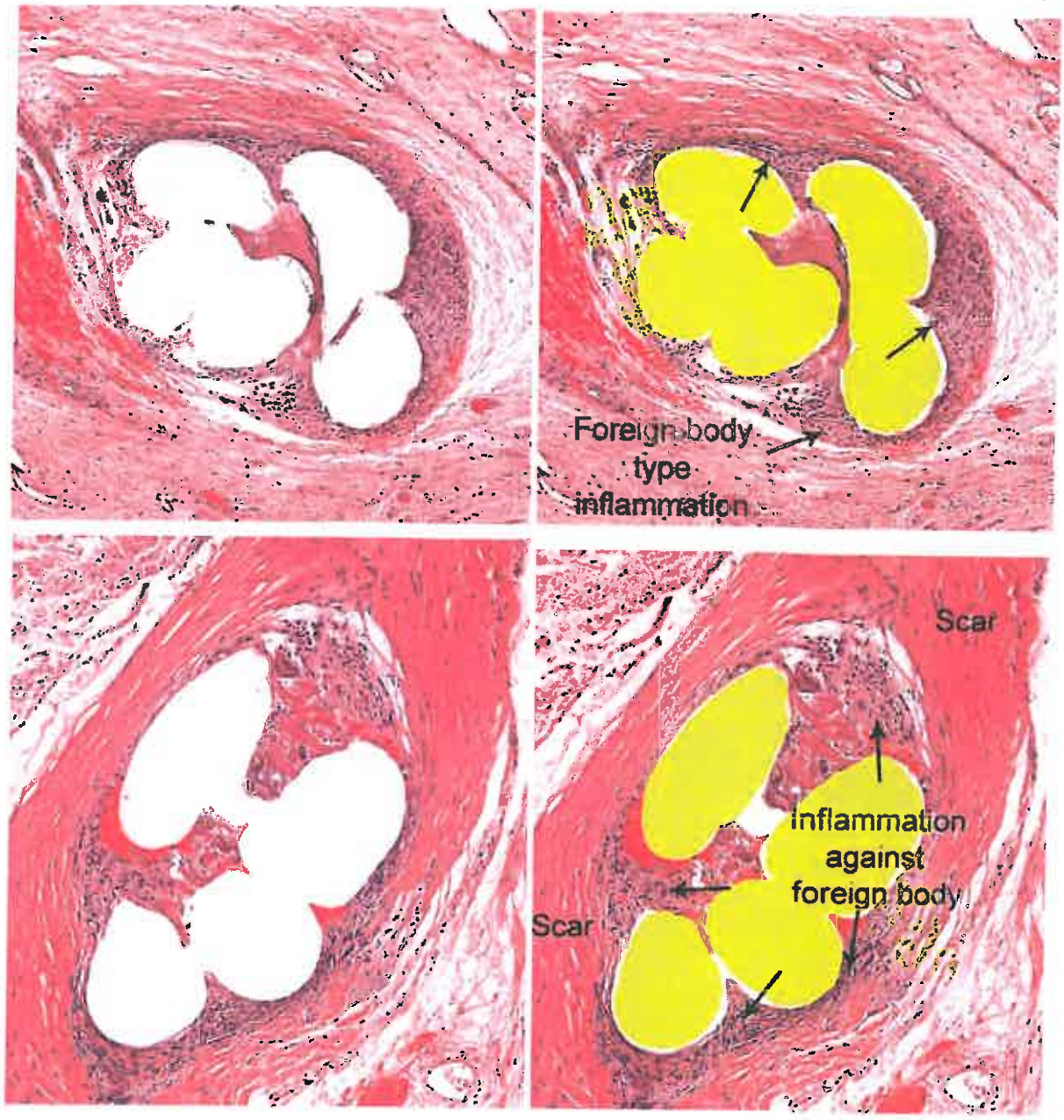


Figure set 1a. Foreign body type inflammatory reaction, H&E, 40x.

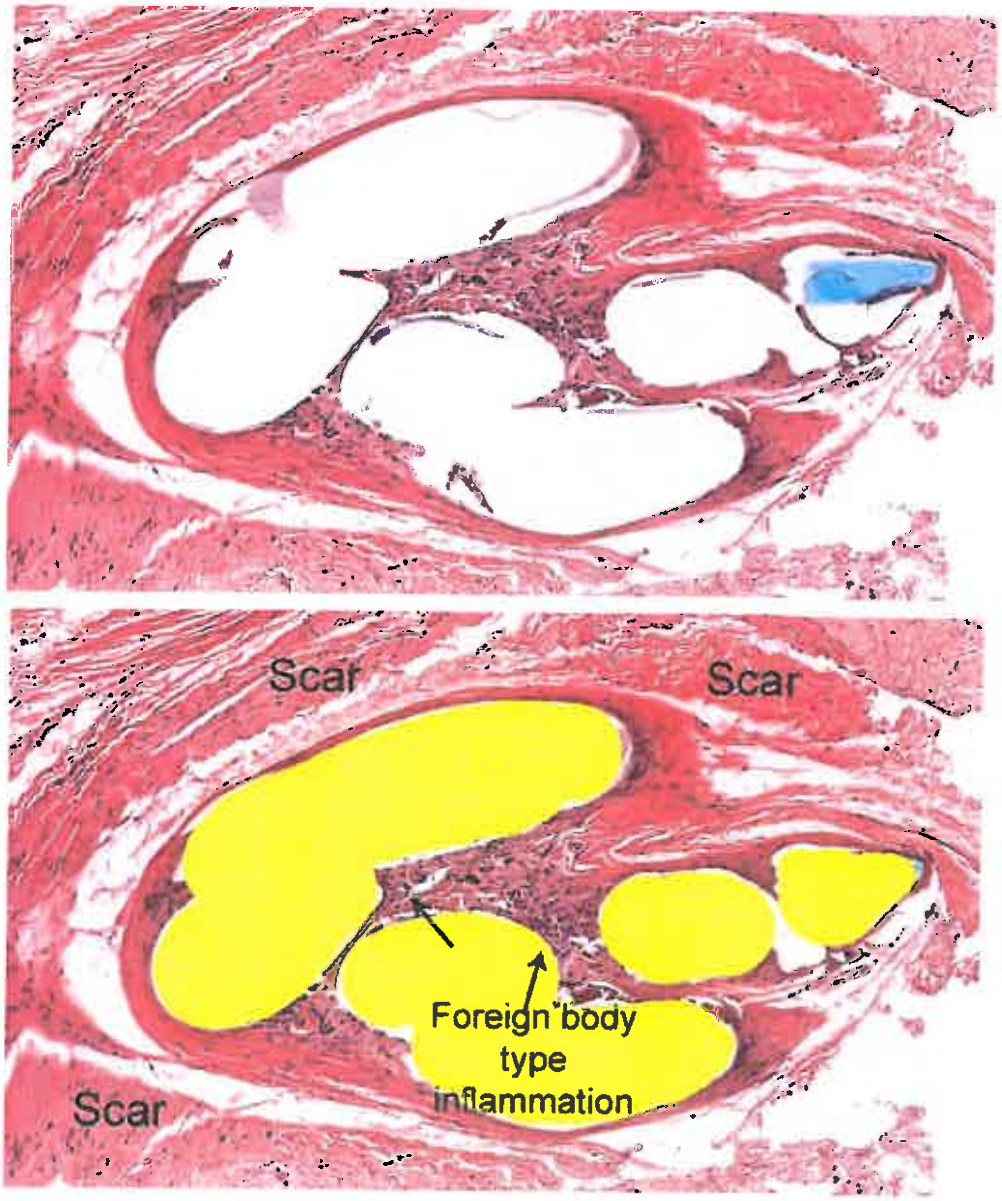


Figure set 1b. Foreign body type inflammatory reaction, H&E, 40x.

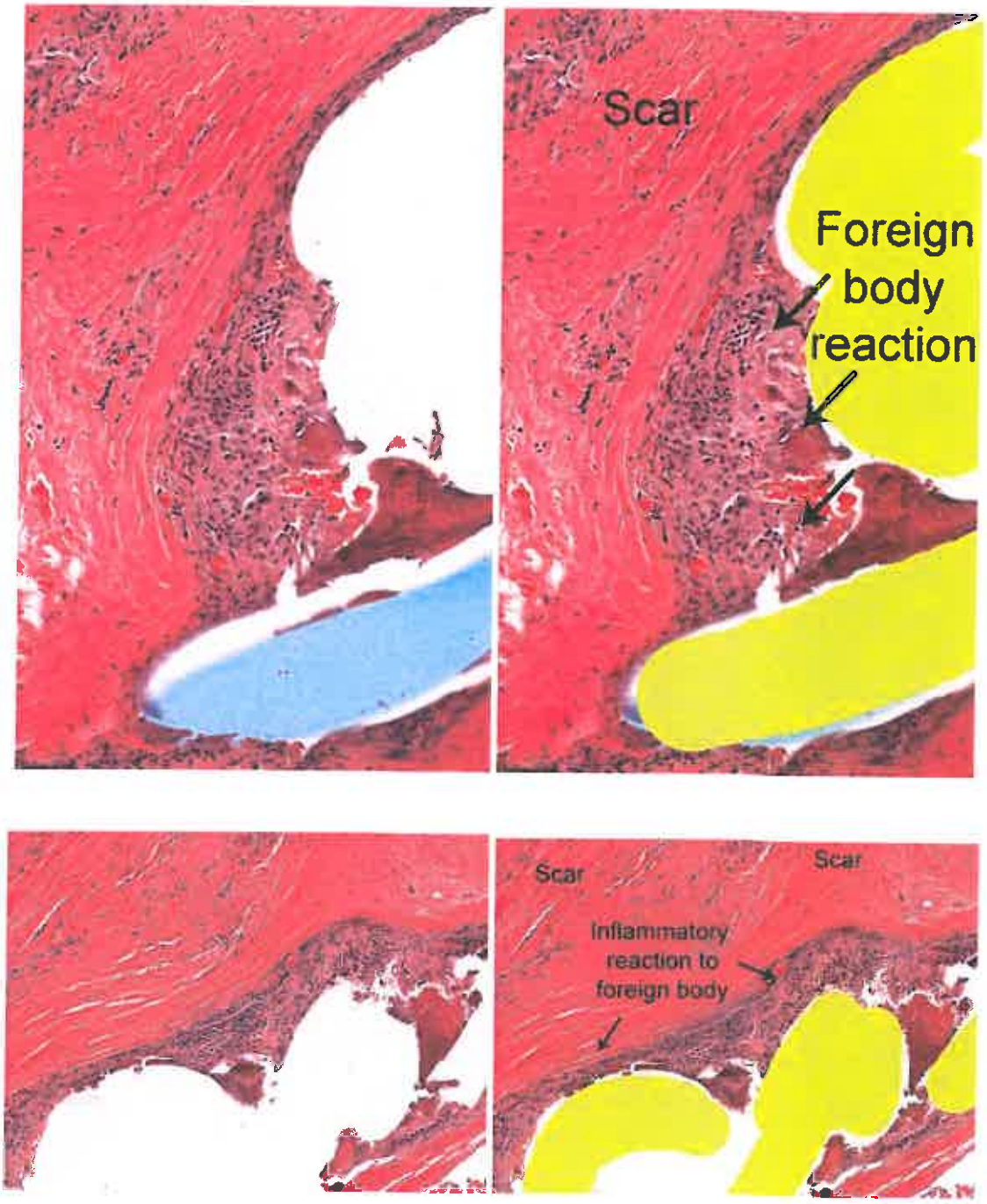


Figure set 1c. Foreign body type inflammatory reaction, H&E,40x.

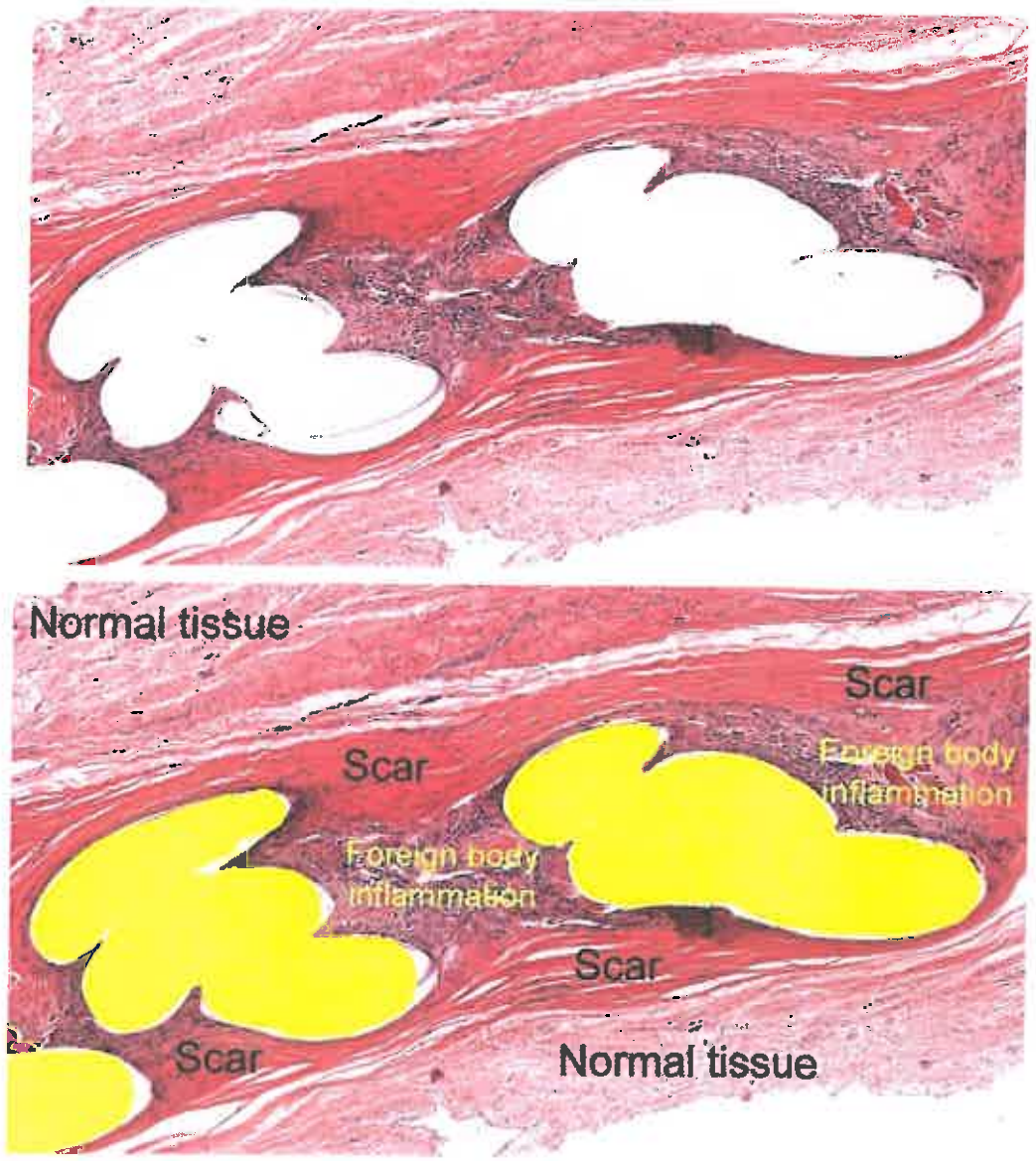


Figure set 2a. Fibrous bridging and scar encapsulation, H&E, 20x.

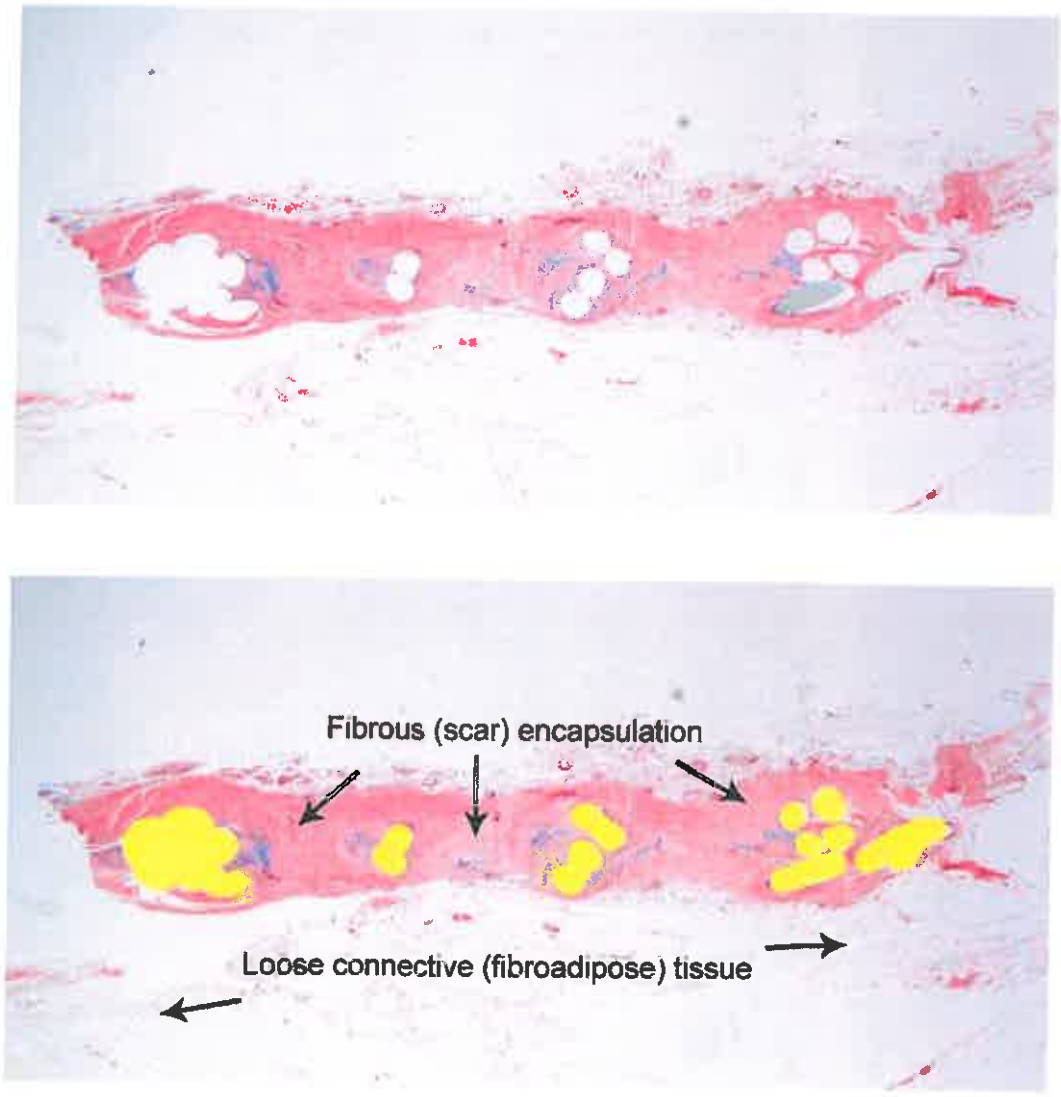


Figure set 2b. Fibrous bridging and scar encapsulation, H&E, 4x.

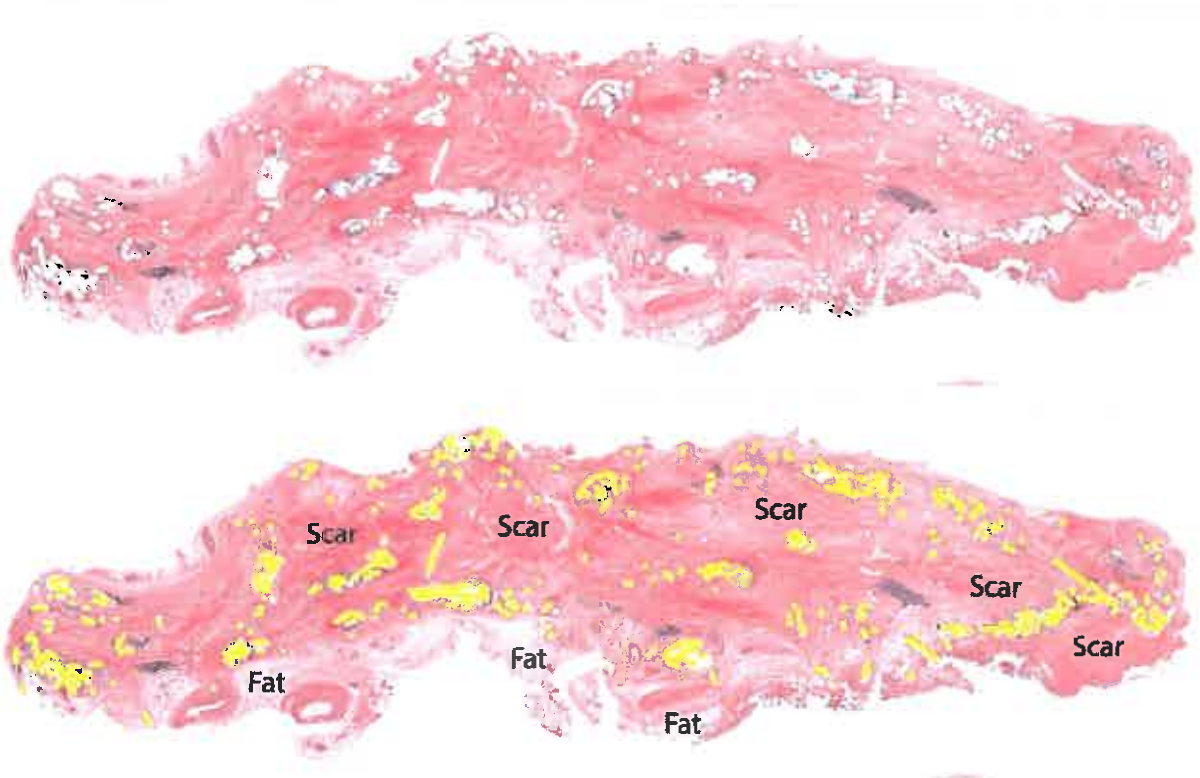


Figure set 2c. Fibrous bridging and scar encapsulation, H&E, 4x.
The mesh is incorporated by scar tissue while normal non scarred adipose tissue (fat) is outside of the mesh-scar plate.

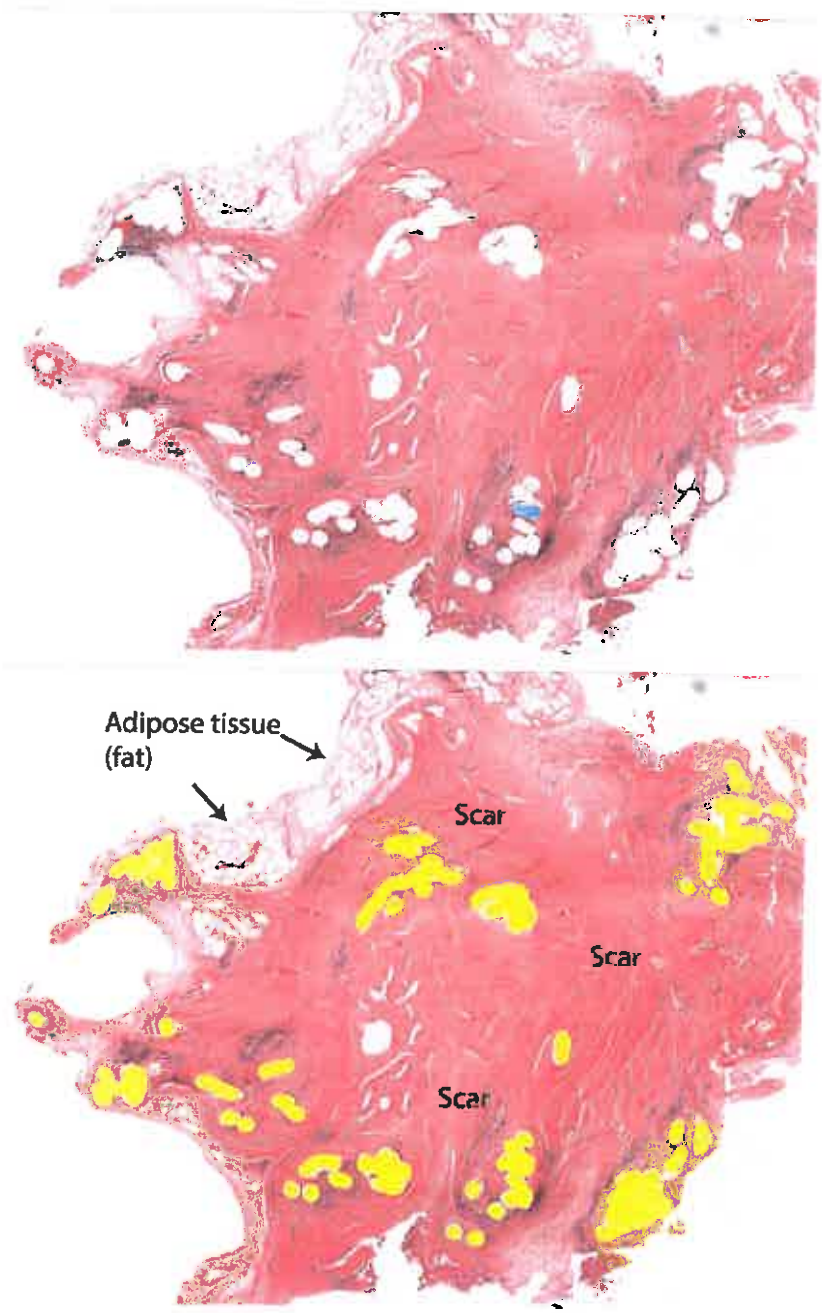


Figure set 2d. Fibrous bridging and scar encapsulation, H&E, 1.6x.

The mesh is incorporated by scar tissue while normal non scarred adipose tissue (fat) is outside of the mesh-scar plate.

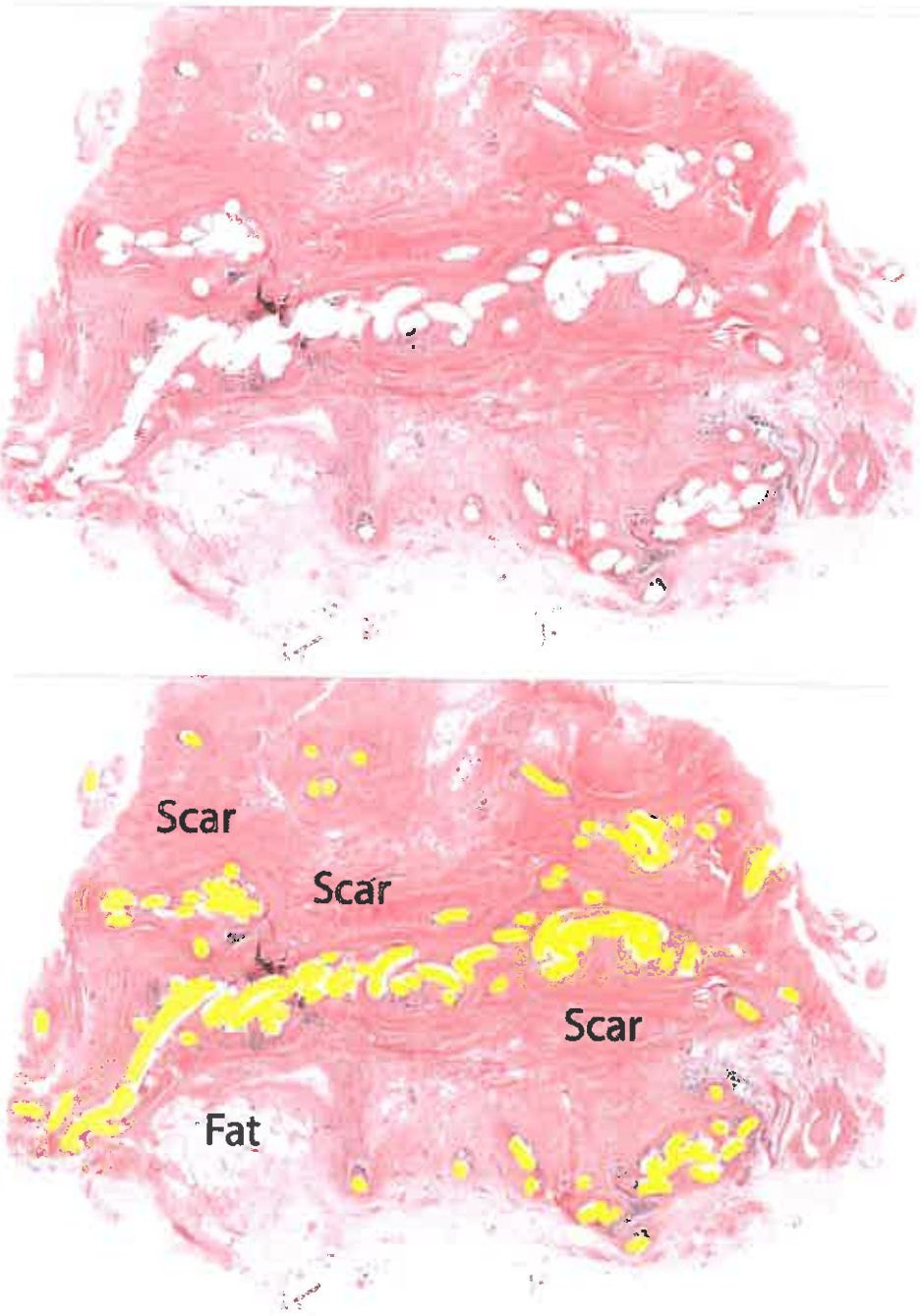


Figure set 2e. Fibrous bridging and scar encapsulation, H&E, 1.6x.

The mesh is incorporated by scar tissue while normal non scarred adipose tissue (fat) is outside of the mesh-scar plate.

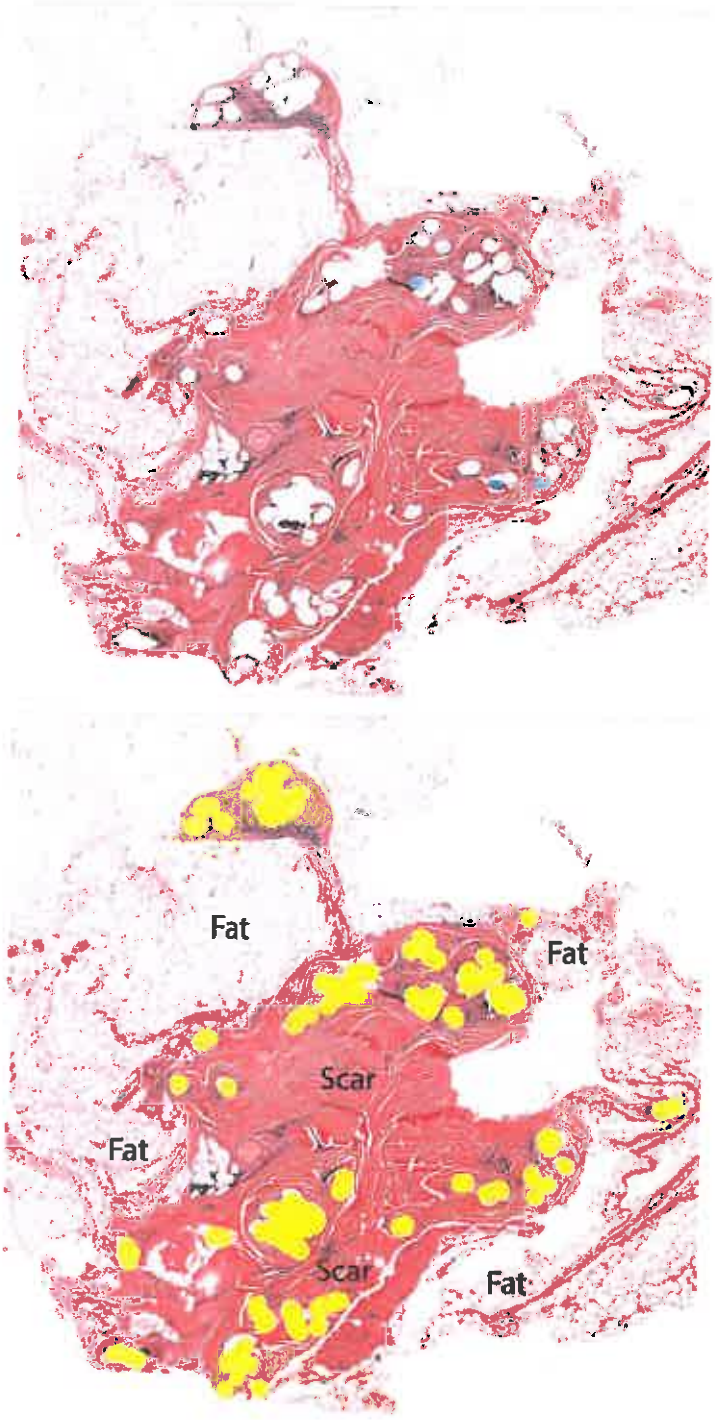


Figure set 2f. Fibrous bridging and scar encapsulation, H&E, 1.6x.
The mesh is incorporated by scar tissue while normal non scarred adipose tissue (fat) is outside of the mesh-scar plate.

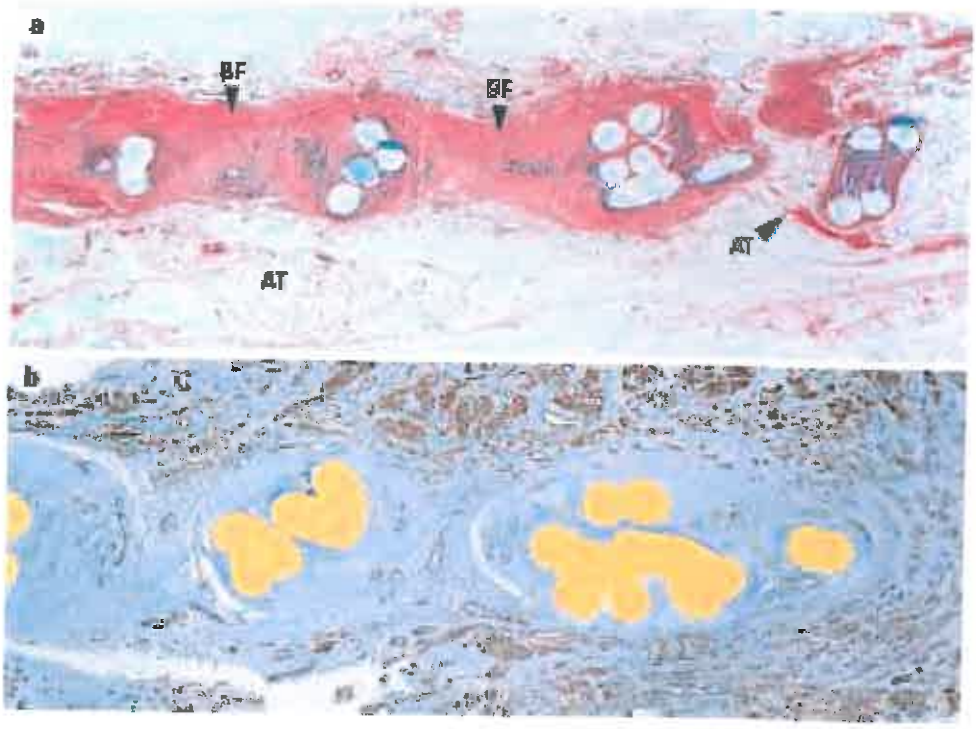


Figure set 2g. Fibrous bridging and scar encapsulation, [557]

"Scar encapsulating mesh and surrounding pre-existent normal adipose and muscular tissues. a | ×2.5 image of a histological section showing a cross-section of mesh filaments as they appear in section, without colouring. Some filaments were labelled blue by the manufacturer. Adipose tissue had been present in the area before mesh placement. Tissue reaction to surgical injury and the mesh generated scar tissue encapsulating the mesh appears as dense pink collagenous tissue. The scar spans, or bridges, across mesh pores, which is termed bridging fibrosis. In this case a terminal pore contains nonscar adipose tissue (arrow with AT). This section has been labelled with a haematoxylin and eosin stain. b | ×2.5 image of a histological section showing cross-sections of mesh filaments. Note that the mesh is surrounded by a halo of fibrous tissue separating it from the pre-existent tissue of the vaginal wall, containing smooth muscle. Smooth muscle is labelled with anti a smooth muscle actin (brown), mesh filaments are filled yellow. The blue colour is a haematoxylin background stain. Abbreviations: AT, adipose tissue; BF, bridging fibrosis".

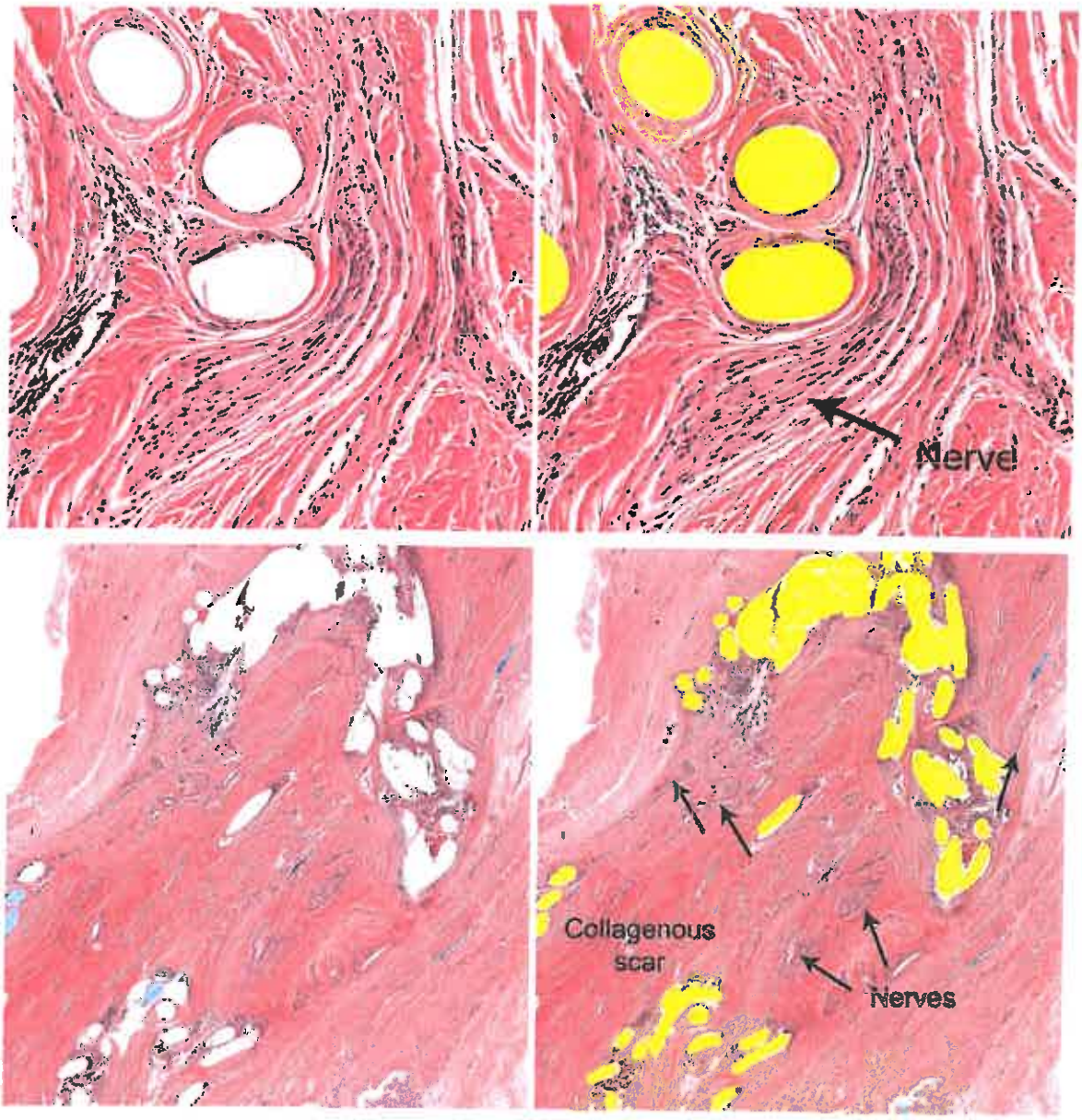


Figure set 3a. Nerves within the mesh spaces (note distortion of the nerve in the upper panel), H&E, 20x and 2.5x.

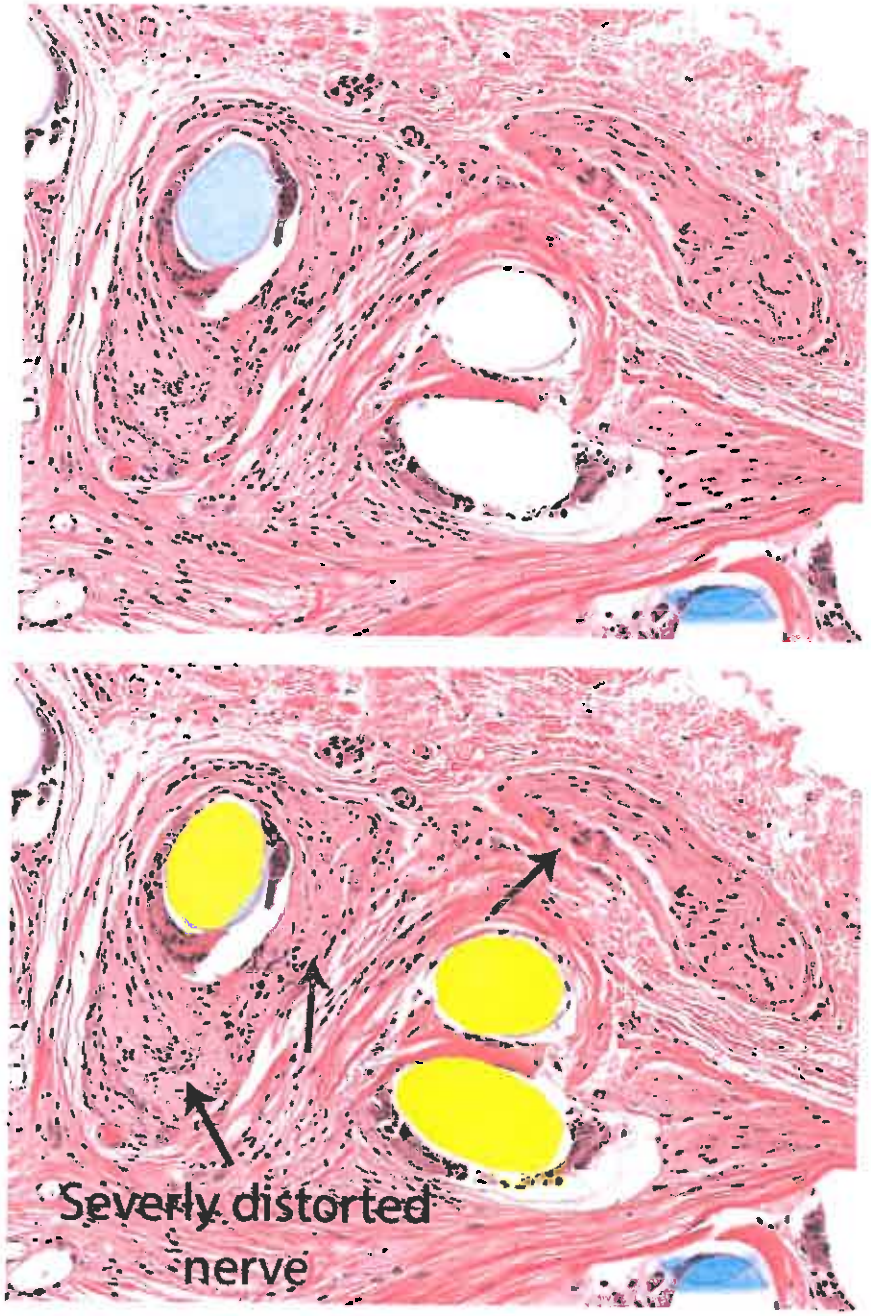


Figure set 3b. Nerves severely distorted by the mesh fibers, H&E, 20x.

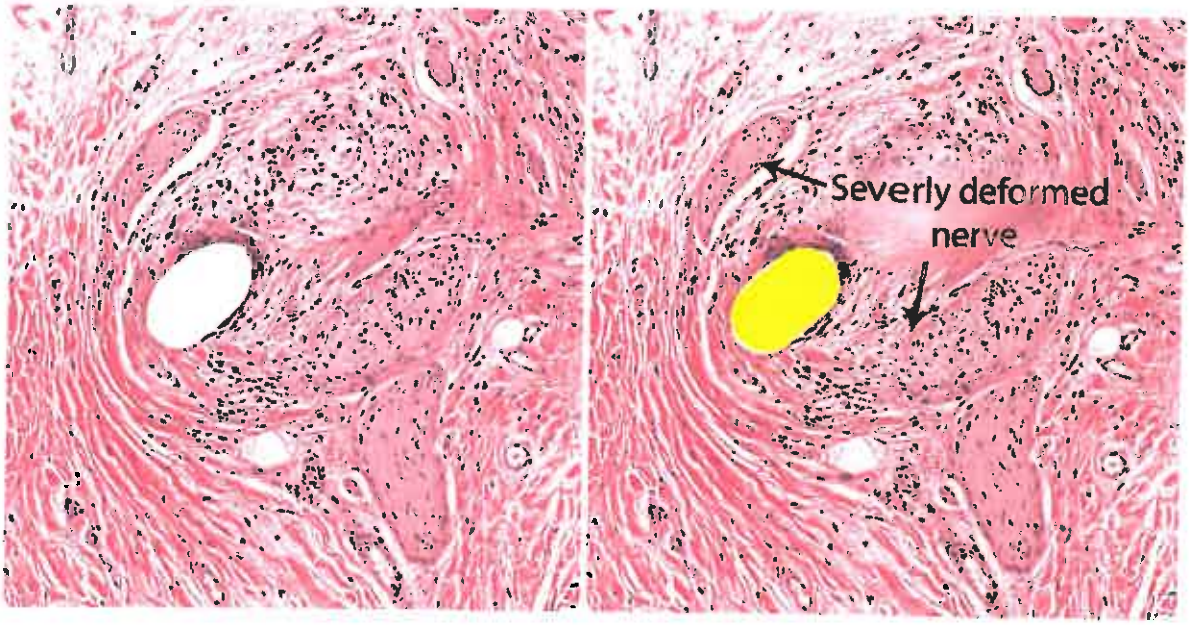


Figure set 3c. Nerves severely distorted by the mesh fibers, H&E, 20x.

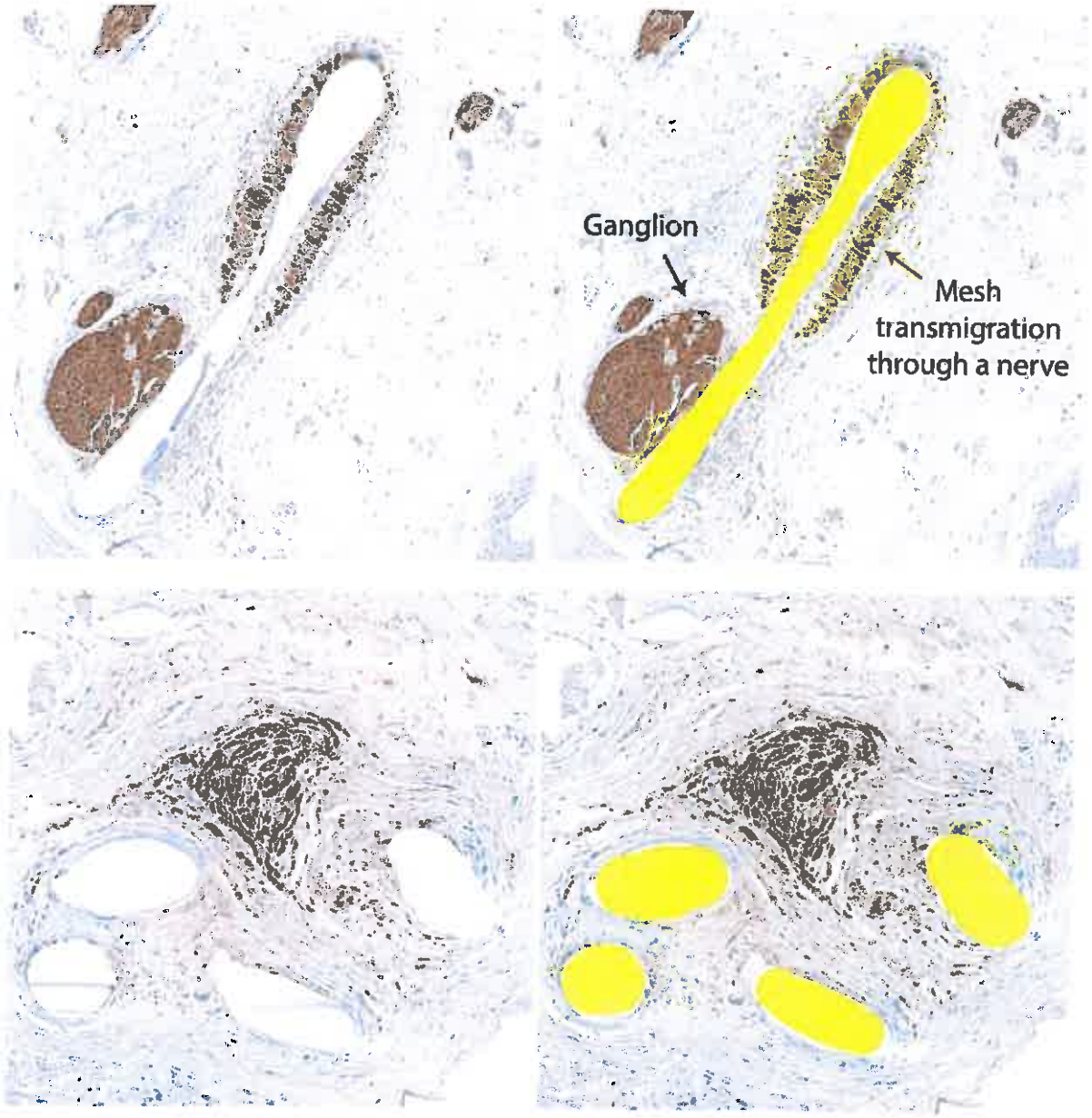


Figure set 3d. Nerves severely damaged by the mesh fibers, H&E, 20x.
The nerve in the upper panel is nearly transected longitudinally. The nerve in the lower panel has separation of the fascicles in the scar tissue = traumatic neuroma.

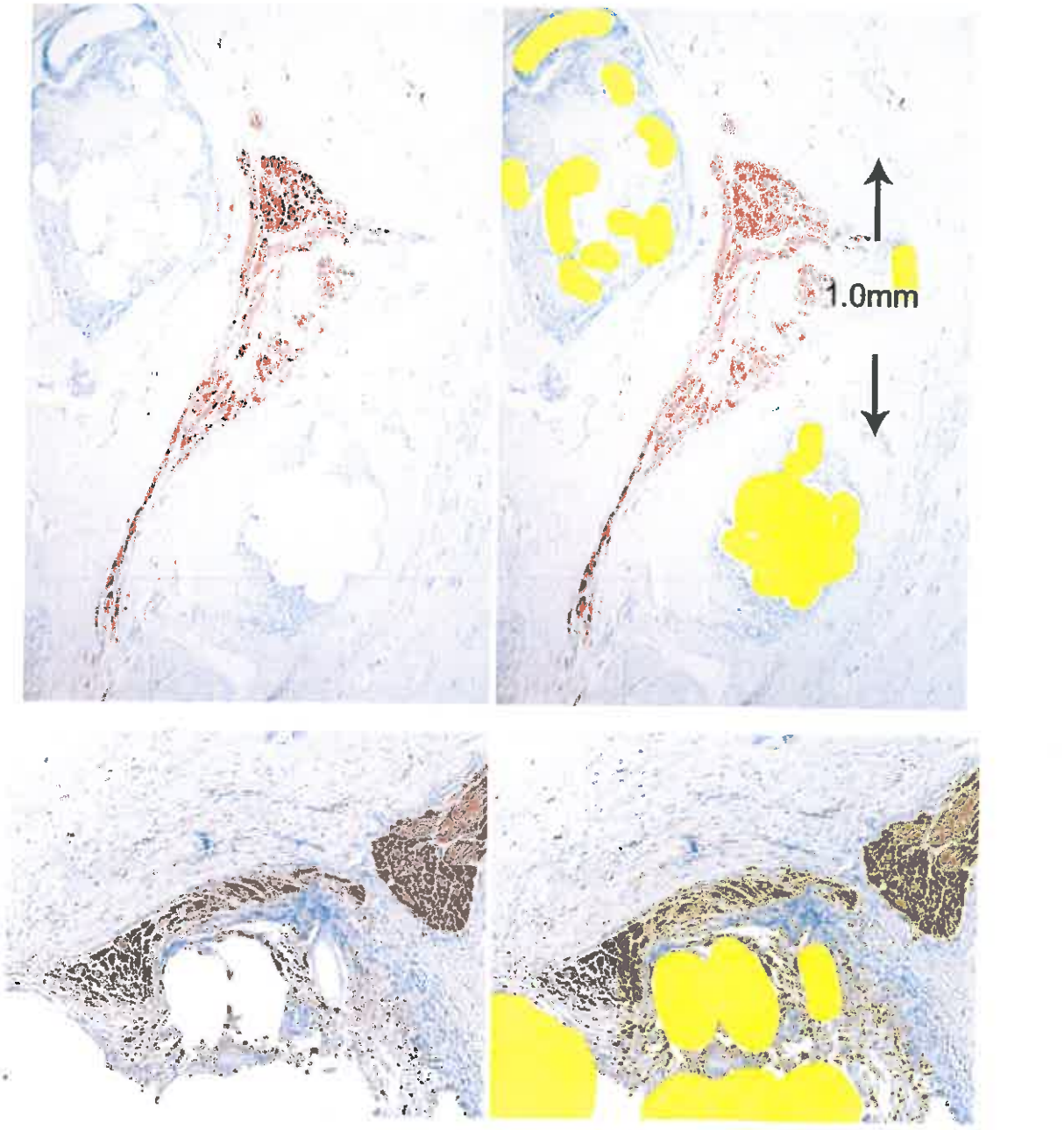


Figure set 3e. Deformation of the nerves and formation of traumatic neuromata, S100, 4x and 10x.

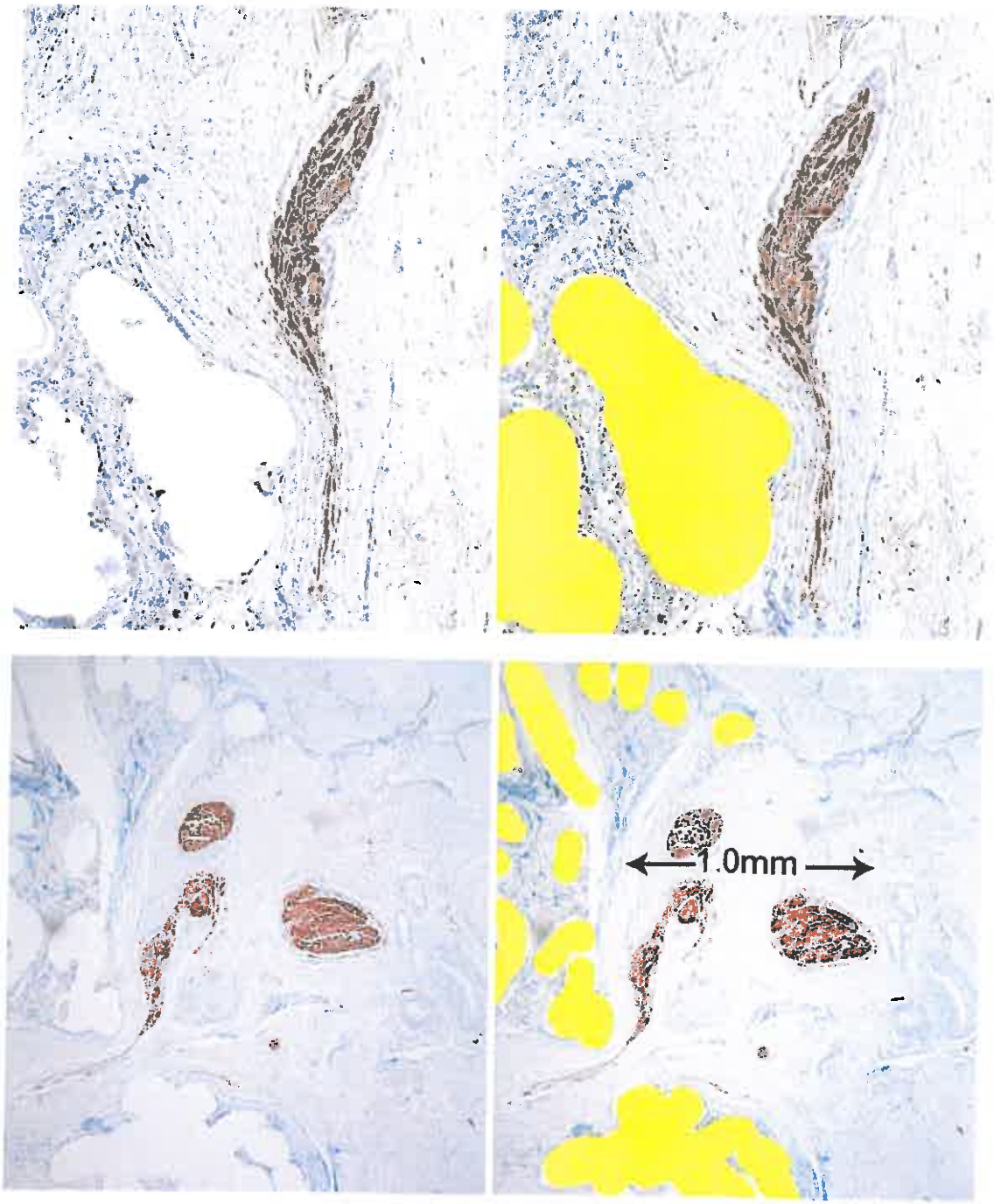


Figure set 3f. Deformation of the nerves, S100, 20x and 10x.

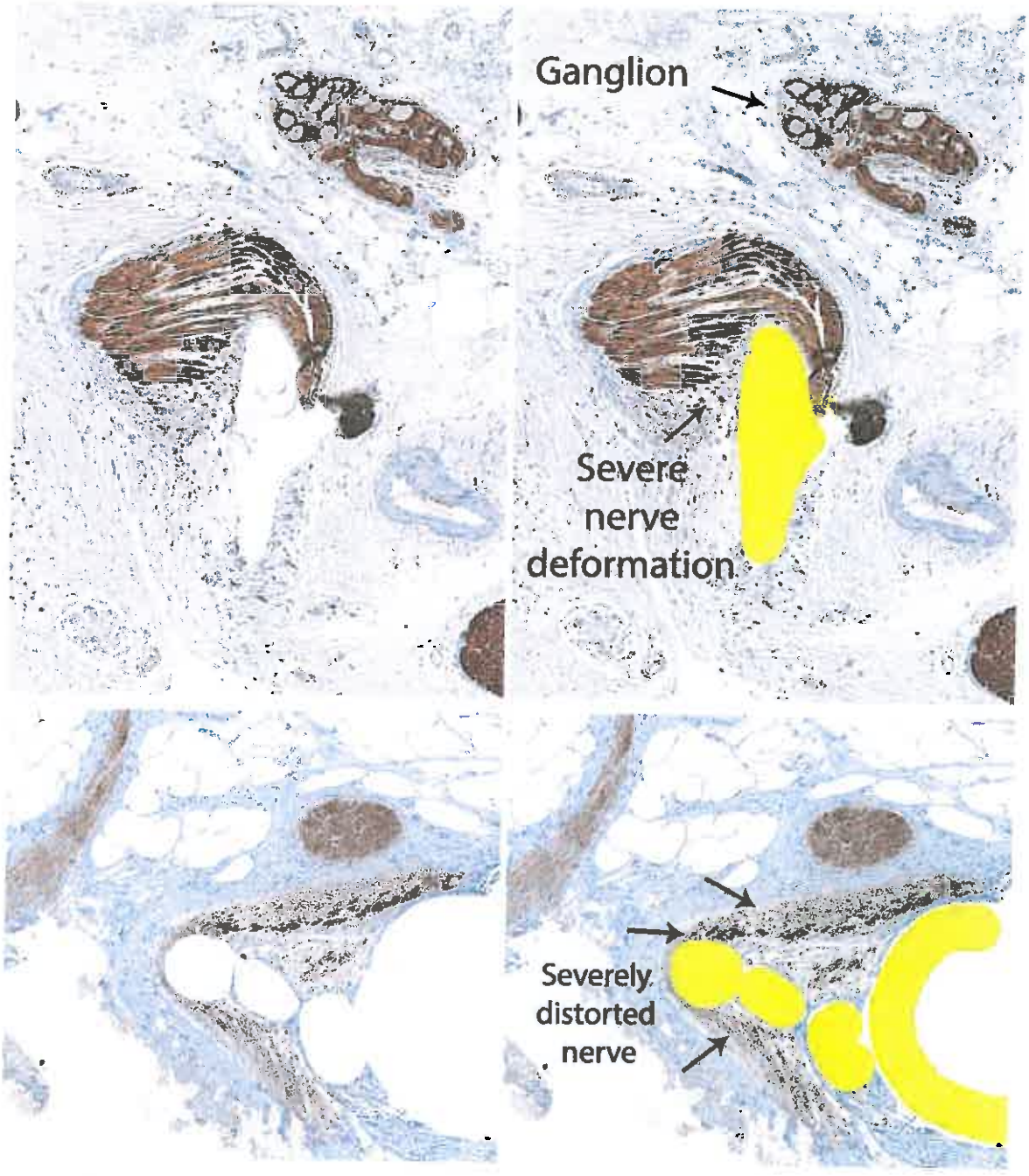


Figure set 3g. Severe deformation of the nerves by the mesh fibers, S100, 20x.

The nerve in the lower panel has separation of the fascicles as occurs in tramatic neuromata.

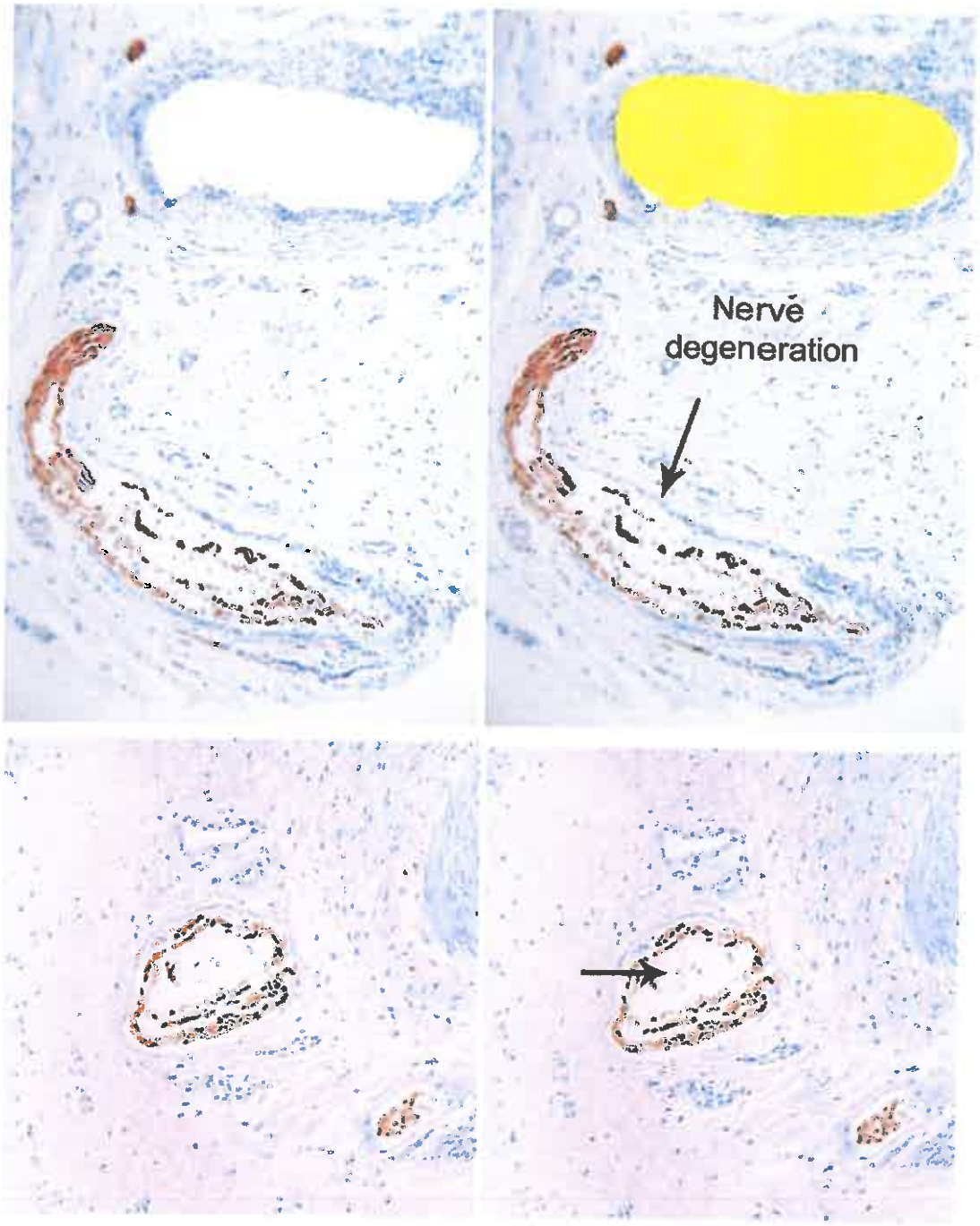


Figure set 3h.Degeneration of affected nerves, s100, 20x,

Degenerative type of changes in peripheral nerves, Renaut bodies have been associated with cronic nerve trauma and entrapment [567-570].

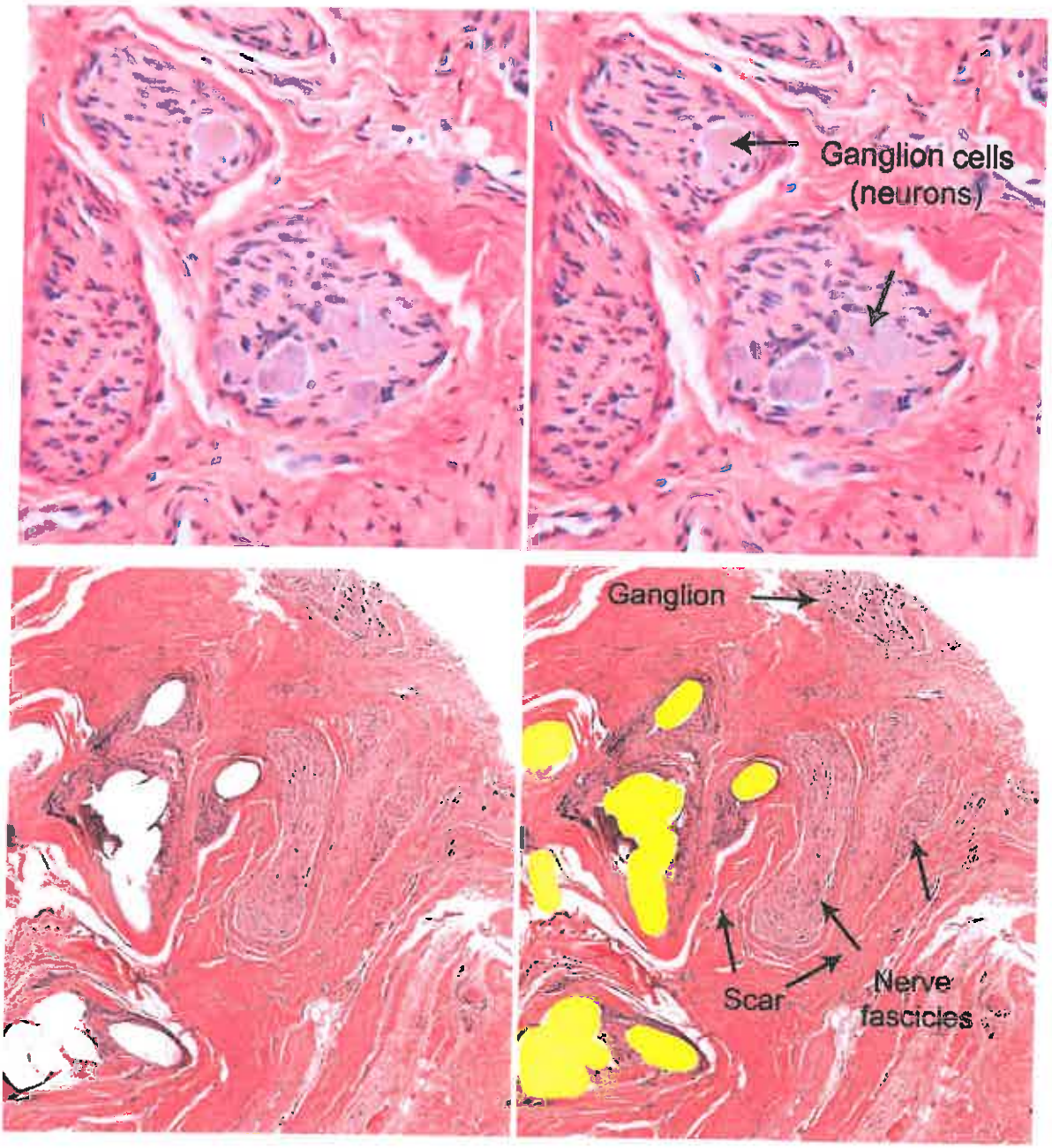


Figure set 4a. Neural ganglia, H&E, 40x and 4x.

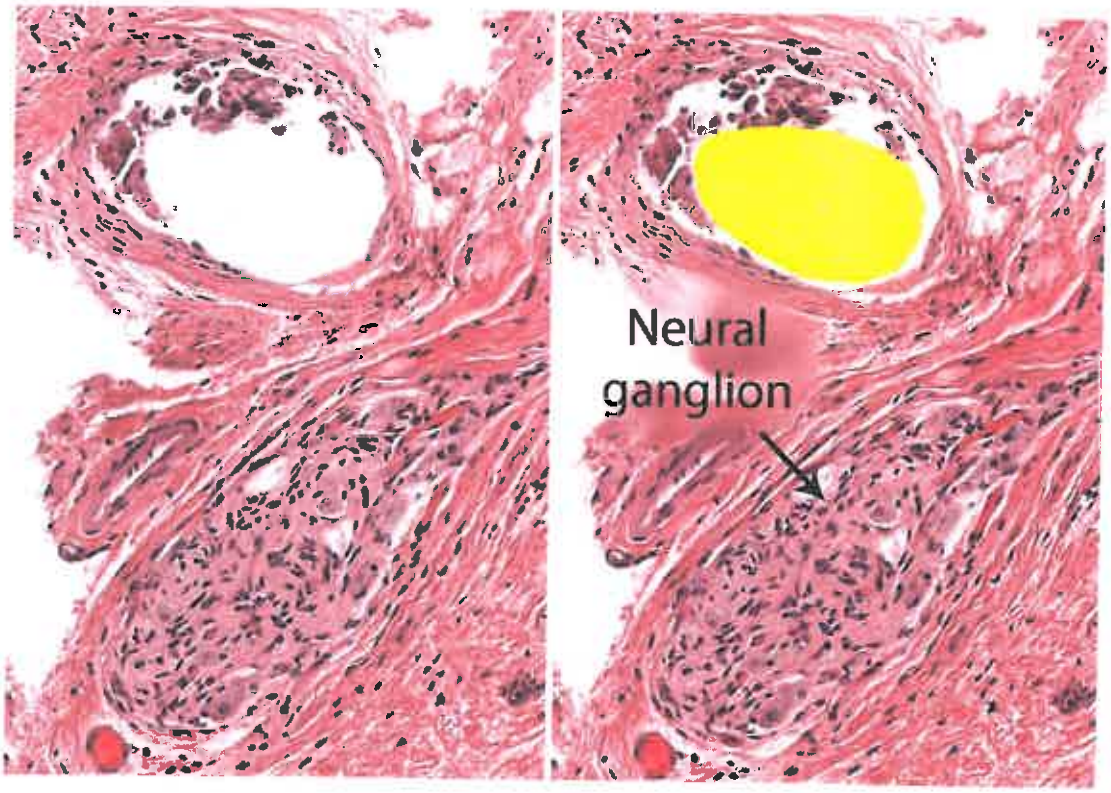


Figure set 4b. Neural ganglion affected by the mesh, H&E, 20x.

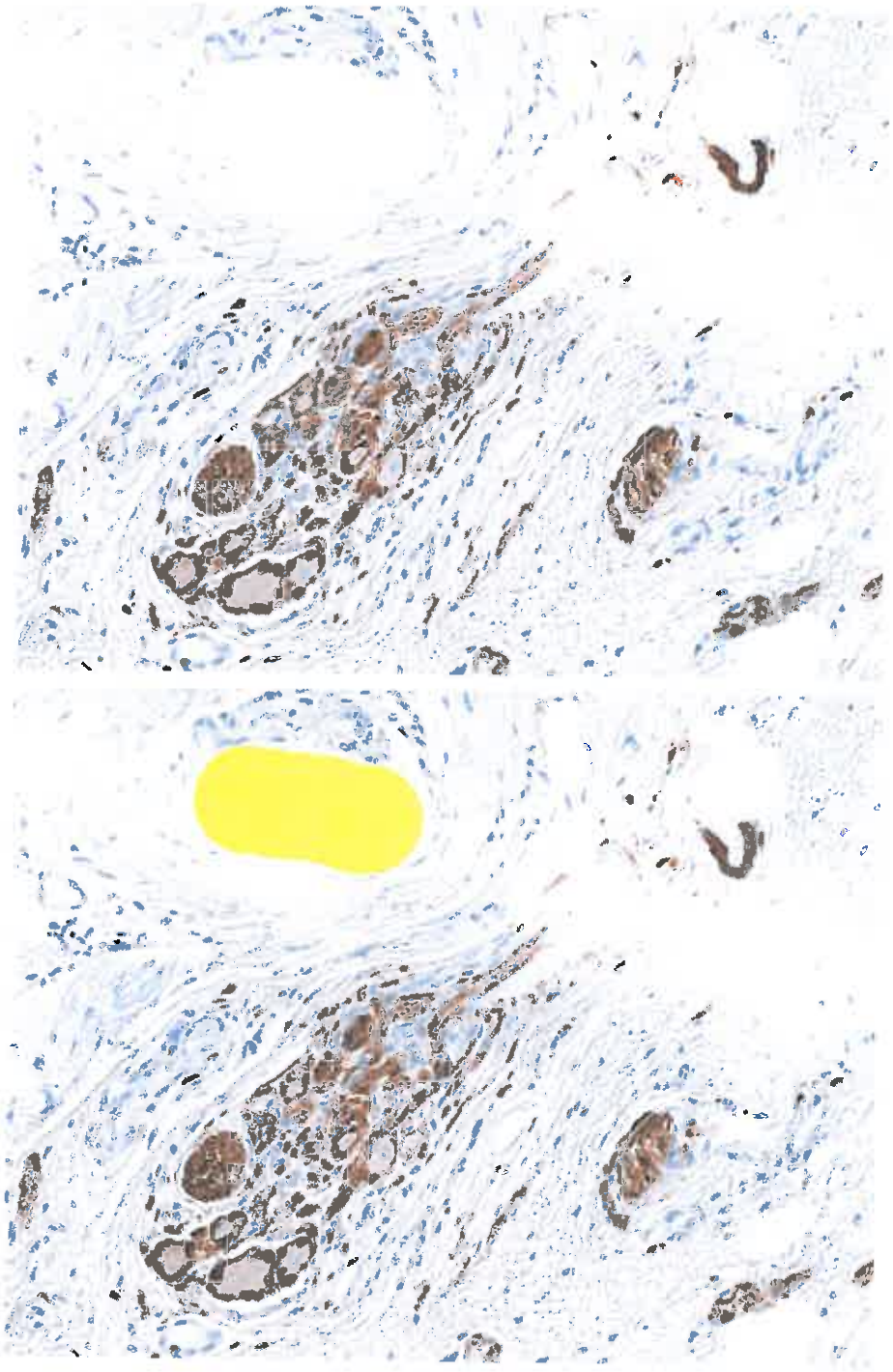


Figure set 4c. Neural ganglion affected by the mesh, H&E, 20x.

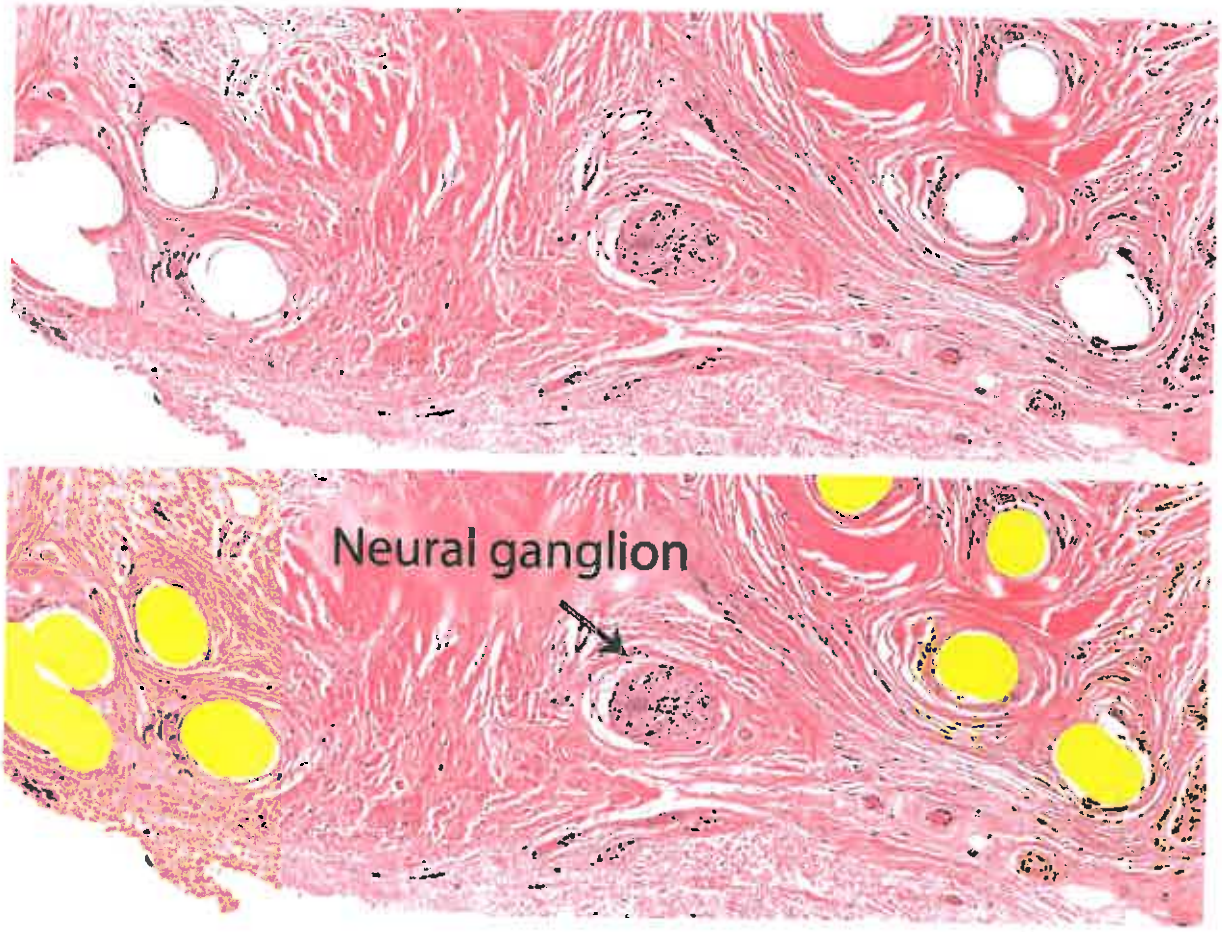


Figure set 4d. Neural ganglion affected by the mesh, H&E, 20x.

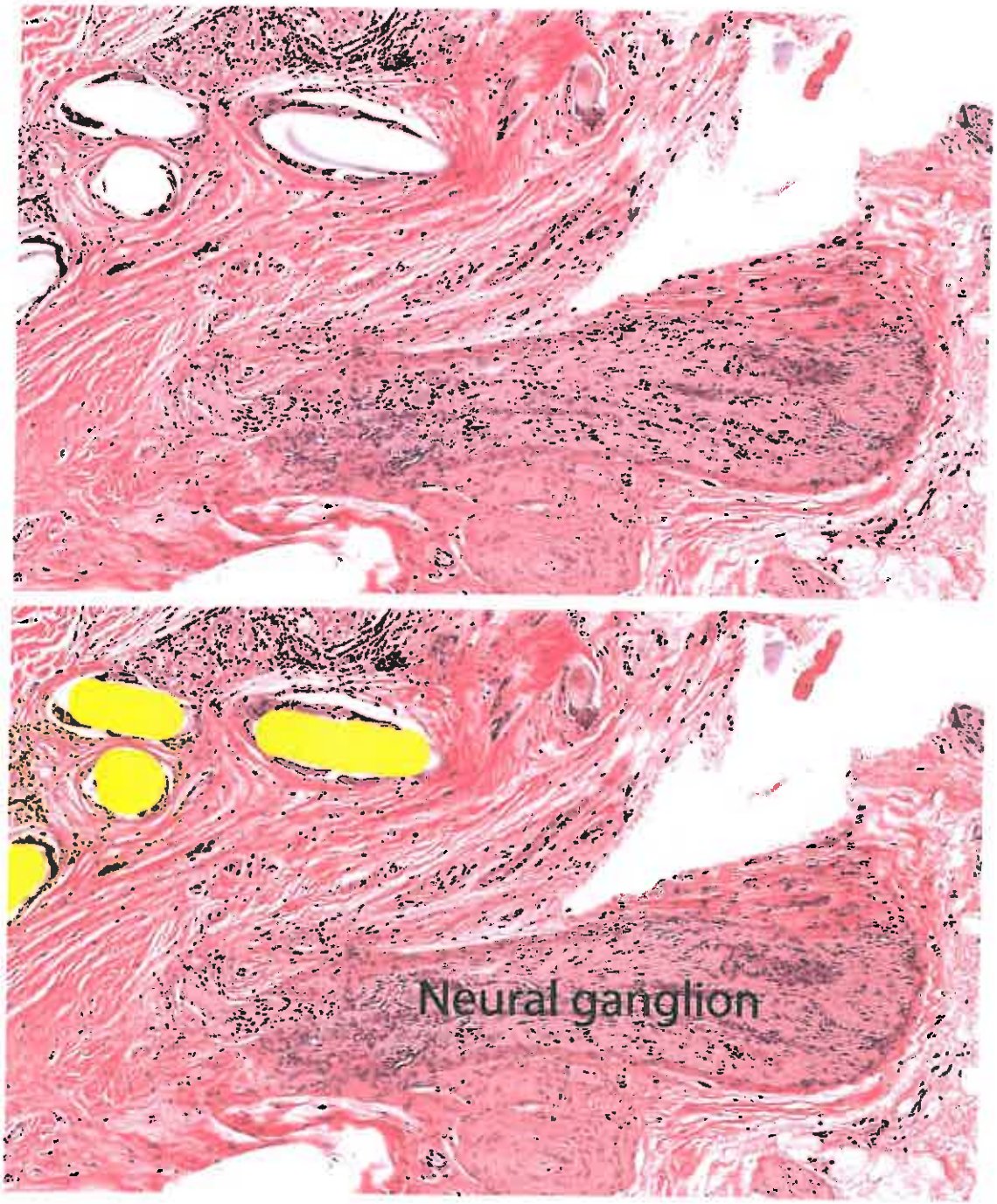


Figure set 4e. Neural ganglion affected by the mesh, H&E, 20x.

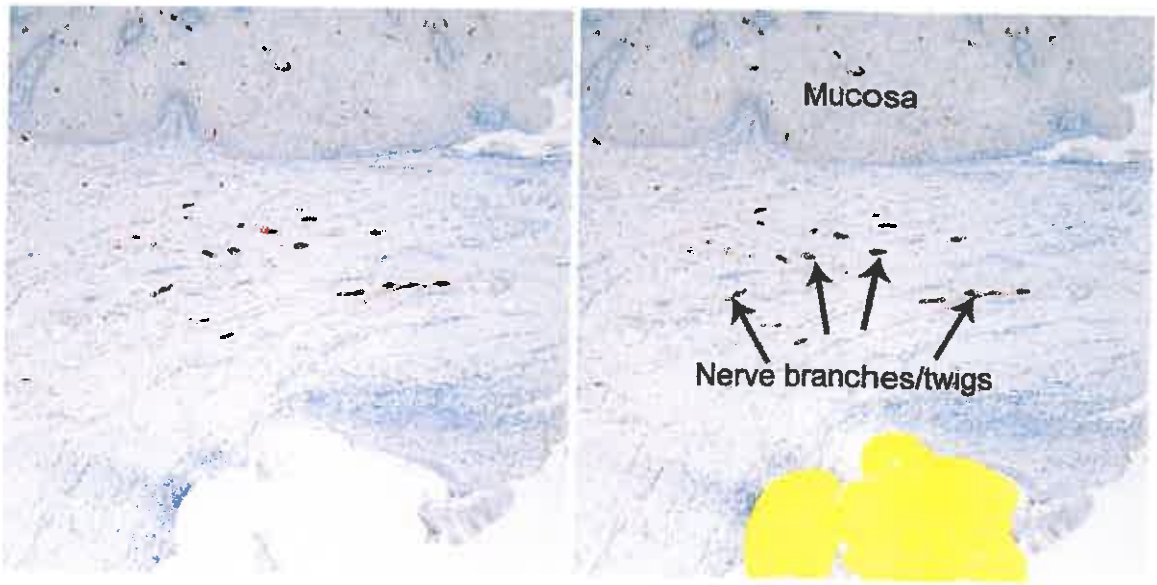


Figure set 5.Innervation of mucosa overlying the mesh, s100, 4x.

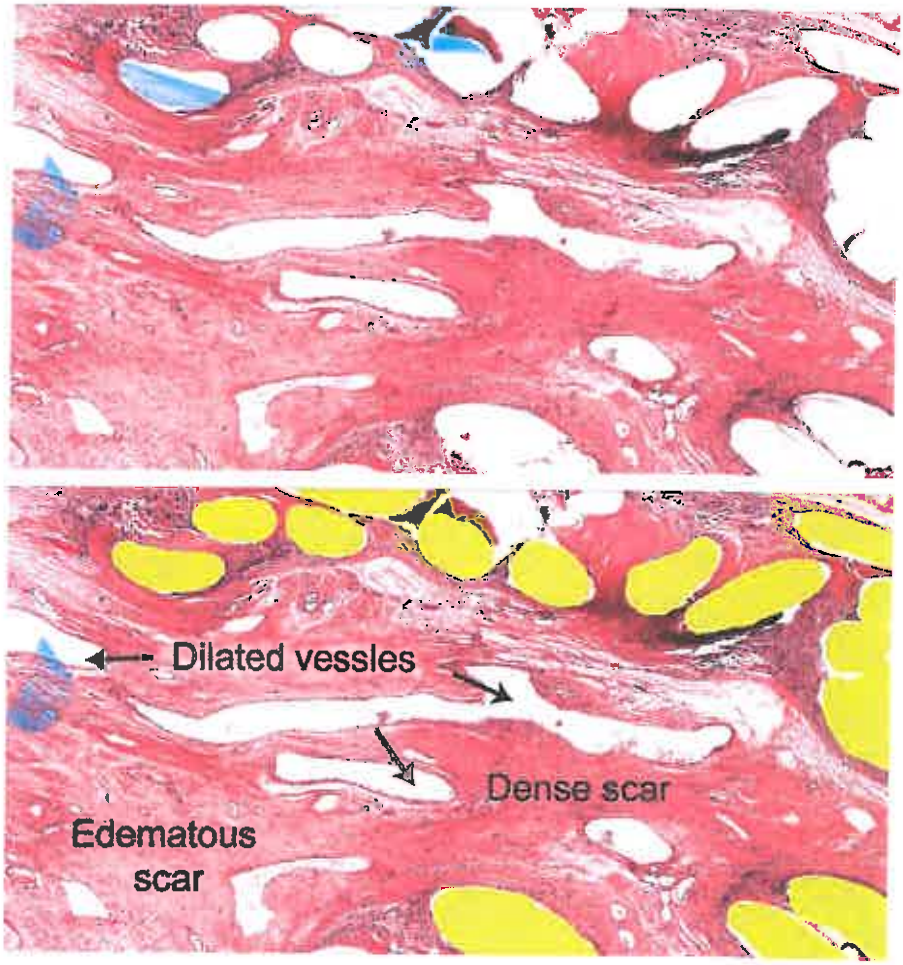


Figure set 6a.Vascular dilatation and tissue edema, H&E, 4x.

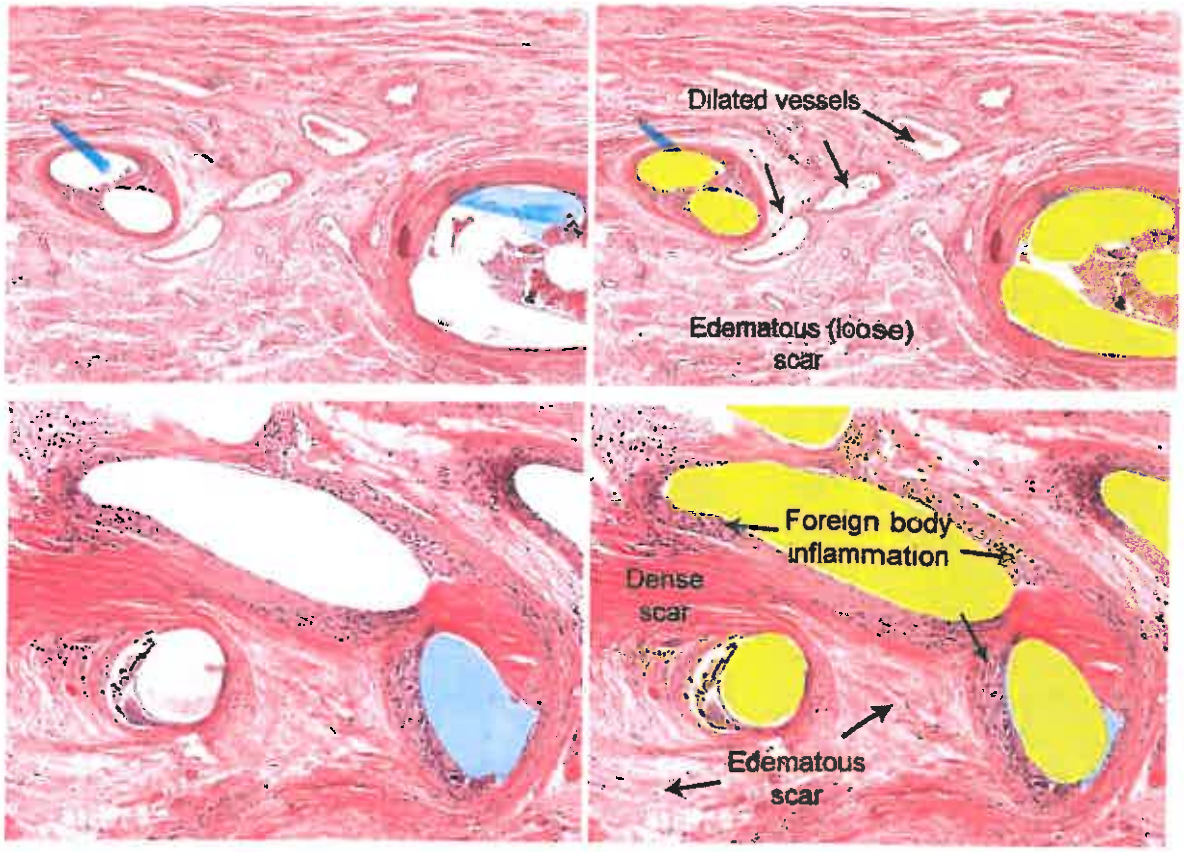


Figure set 6b. Vascular dilatation and tissue edema, H&E, 4x and 10x.

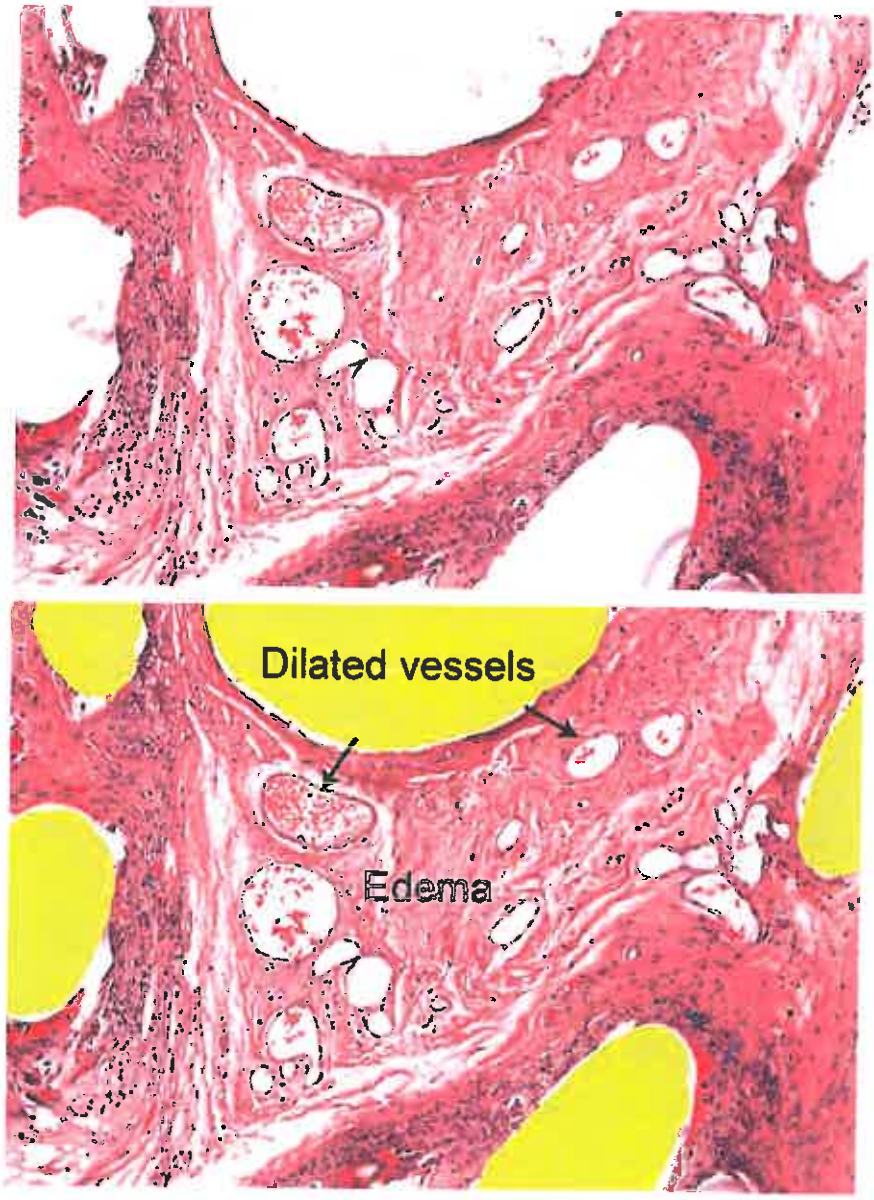


Figure set 6c. Vascular dilatation and tissue edema, H&E, 10x.

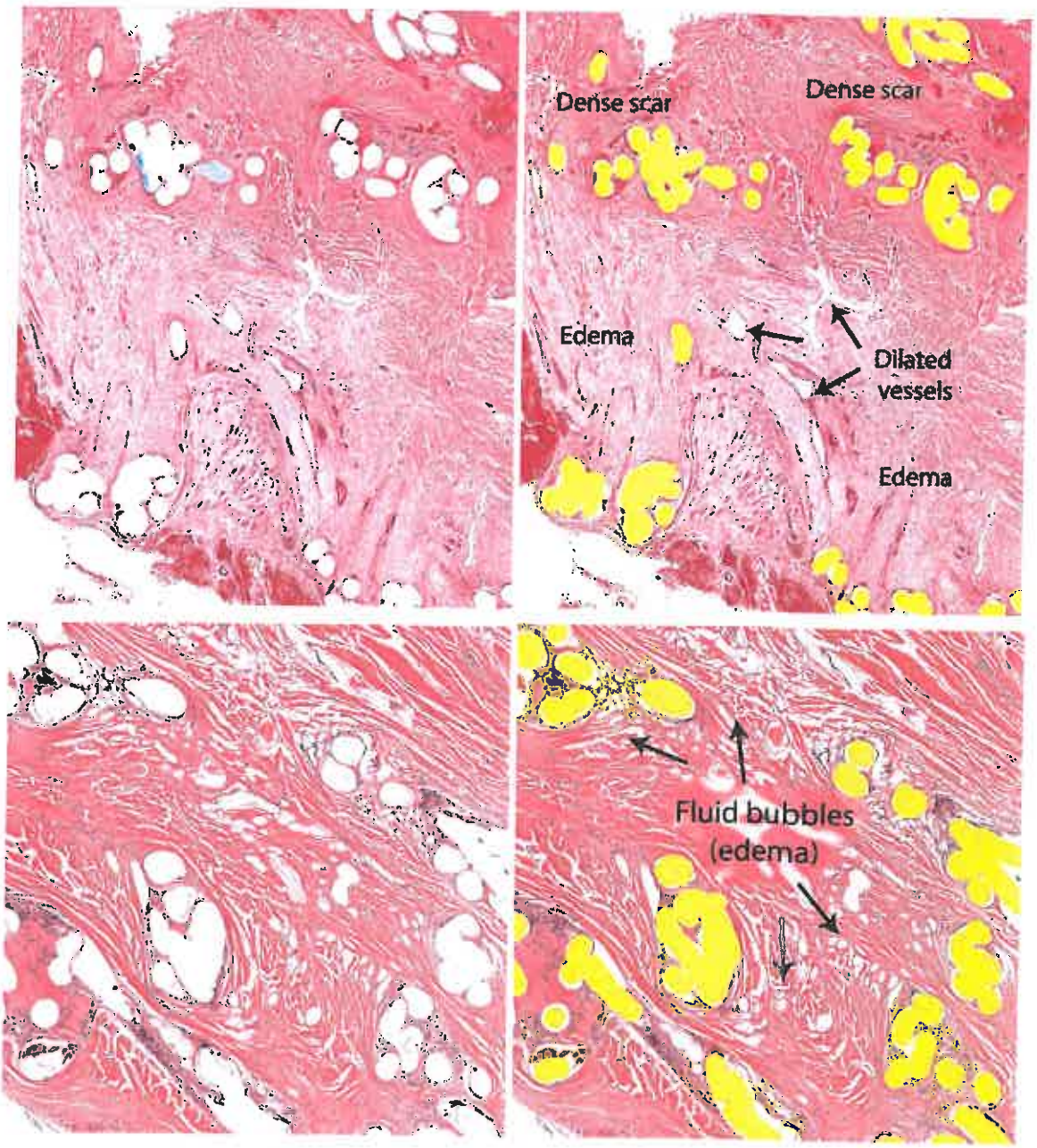


Figure set 6d. Vascular dilatation and tissue edema, H&E, 10x.

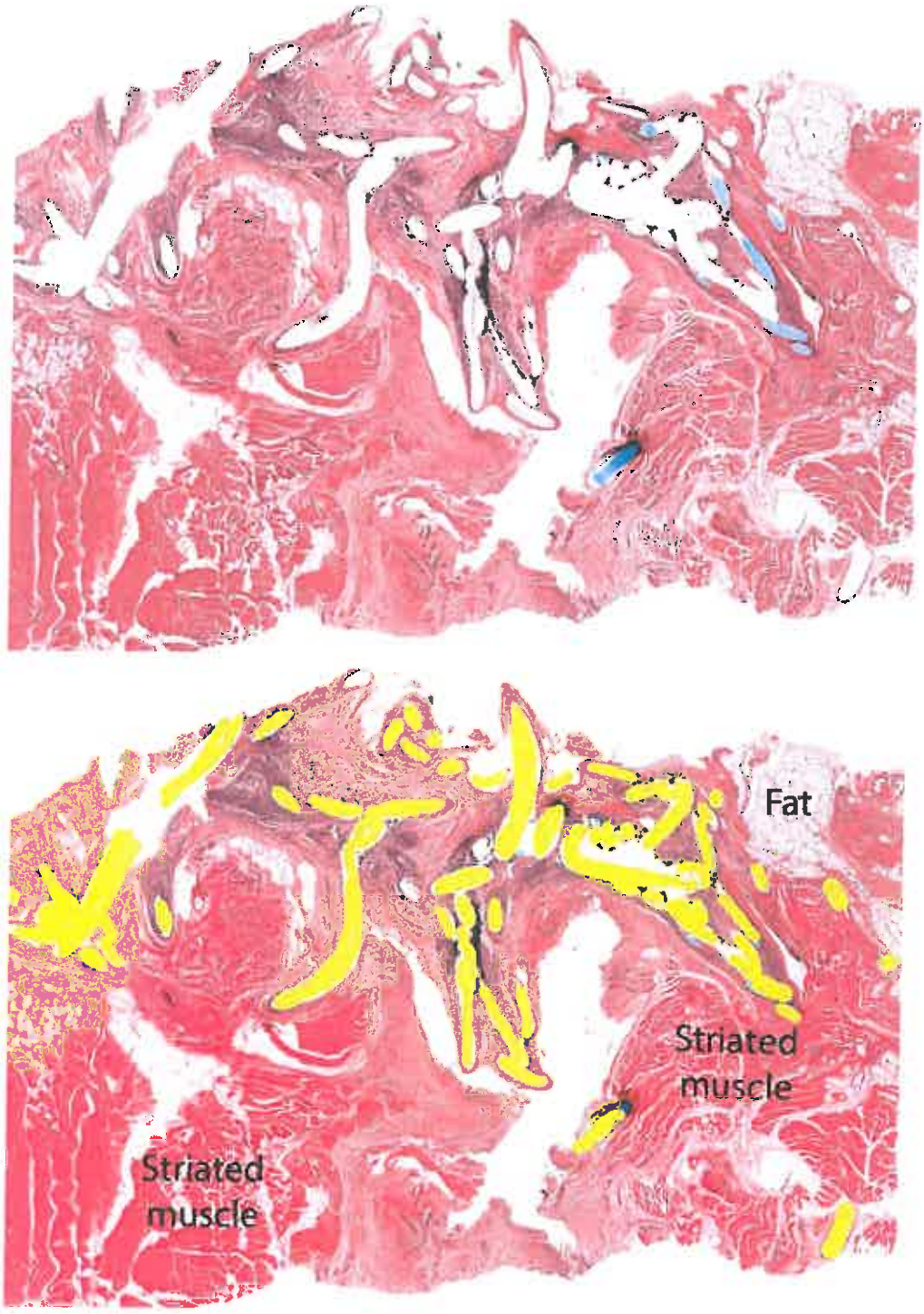


Figure set 7a.Involvement of striated muscle by the mesh, H&E, 1.6x

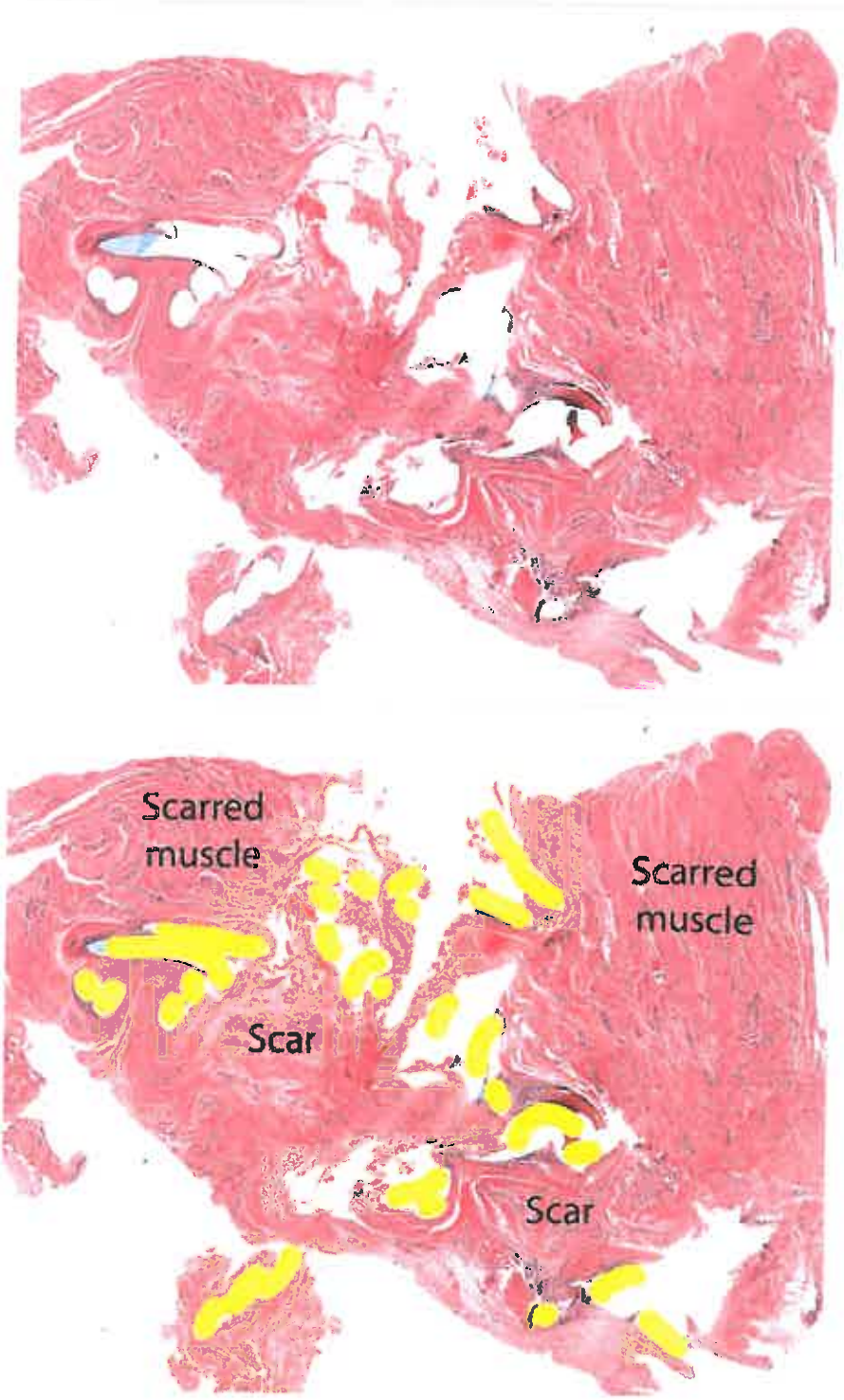


Figure set 7b.Involvement of striated muscle by the mesh, H&E, 1.6x

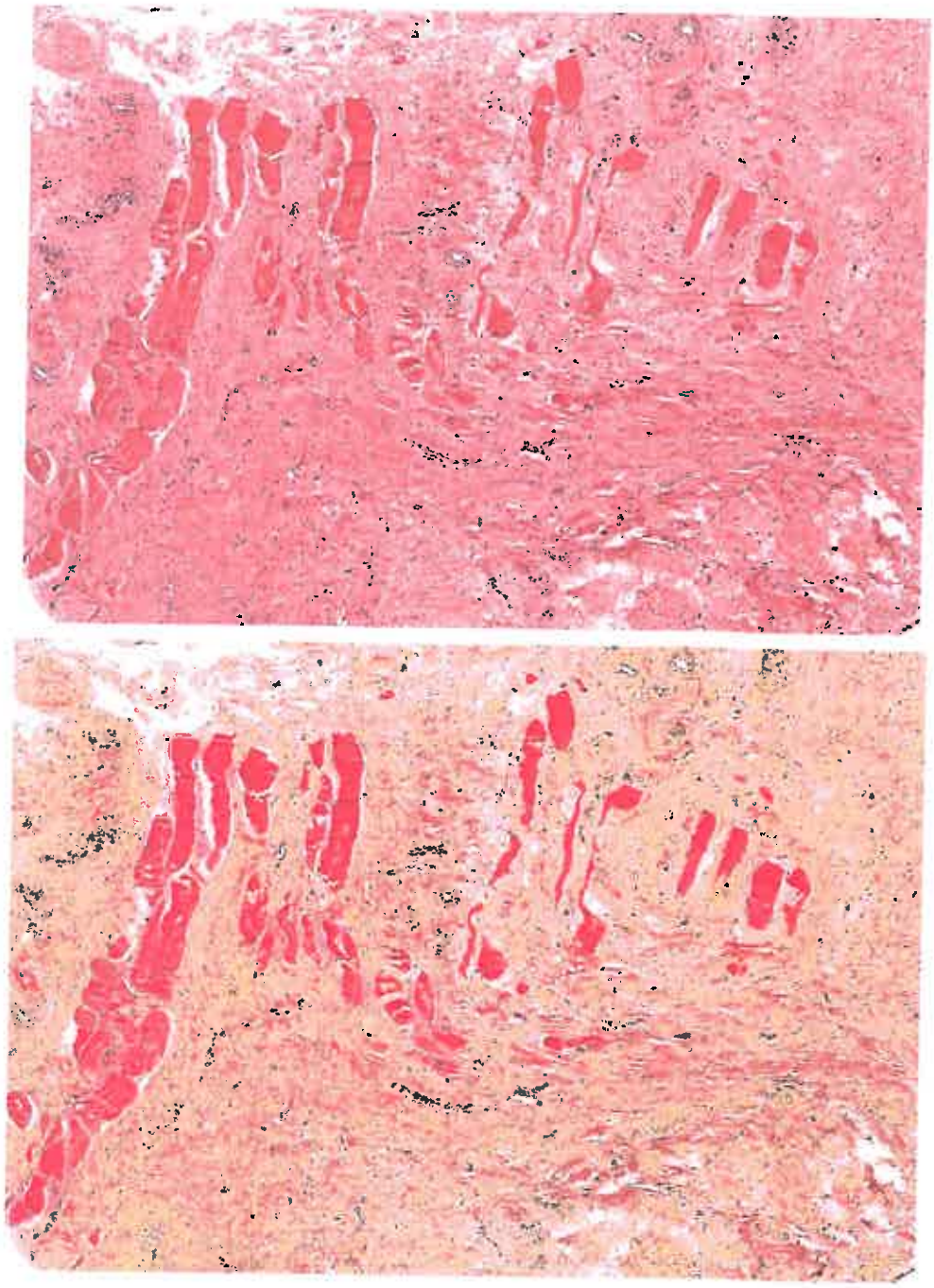


Figure set 7c.Scarring of striated muscle at the mesh, H&E, 4x

Scra tissue highlighted yellow and muscle fibers red in the lower copy of the image.

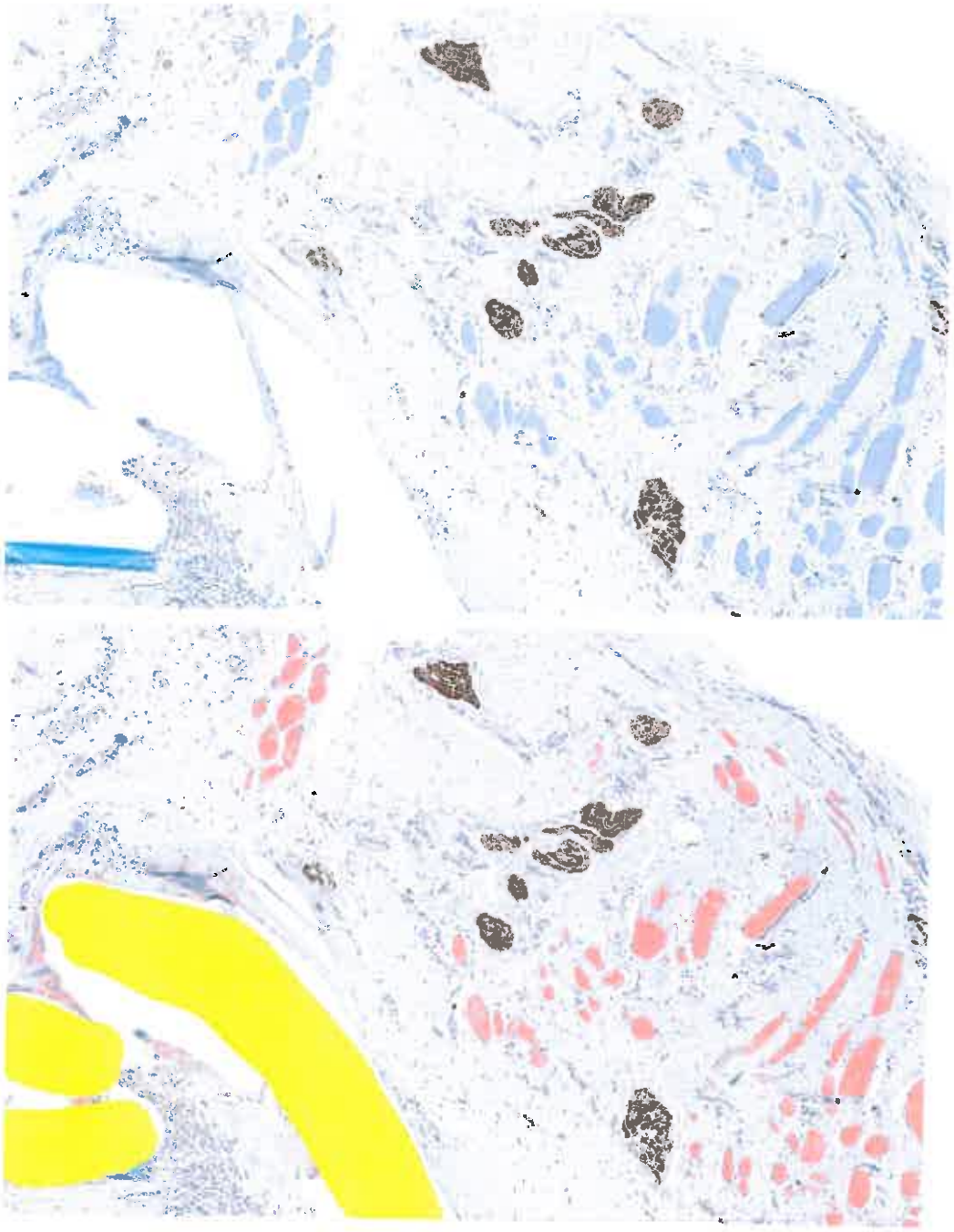


Figure set 7d. Interposition of nerves, scar and damaged striated muscle in the mesh-scar plate, S100, 10x

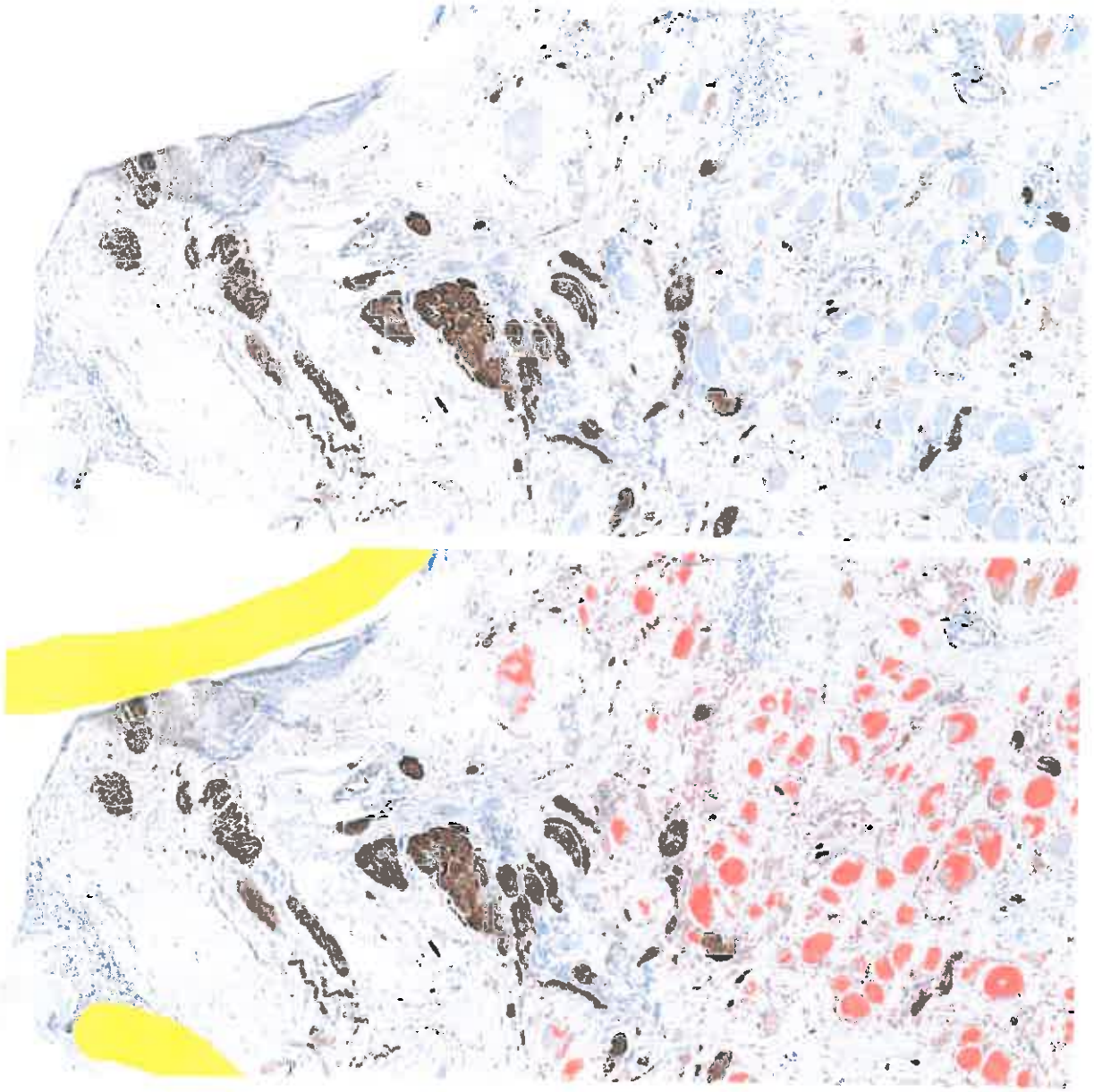


Figure set 7e. Interposition of nerves, scar and damaged striated muscle in the mesh-scar plate, S100, 10x

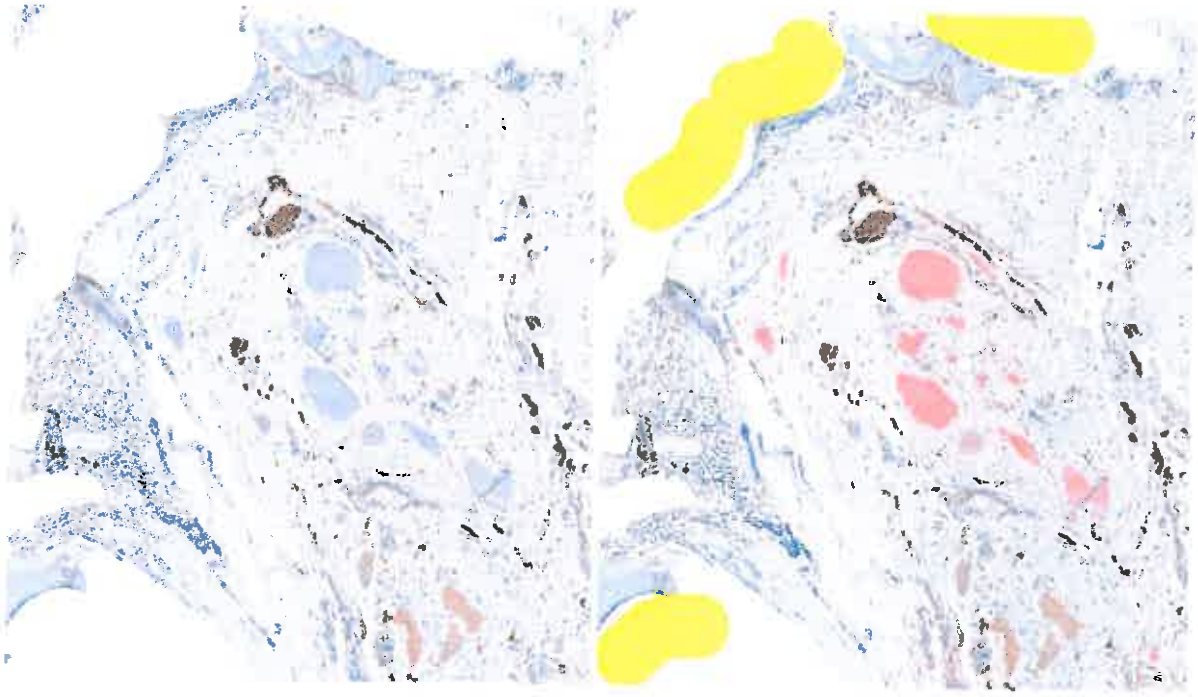


Figure set 7f. Interposition of nerves, scar and damaged striated muscle in the mesh-scar plate, S100, 4x.

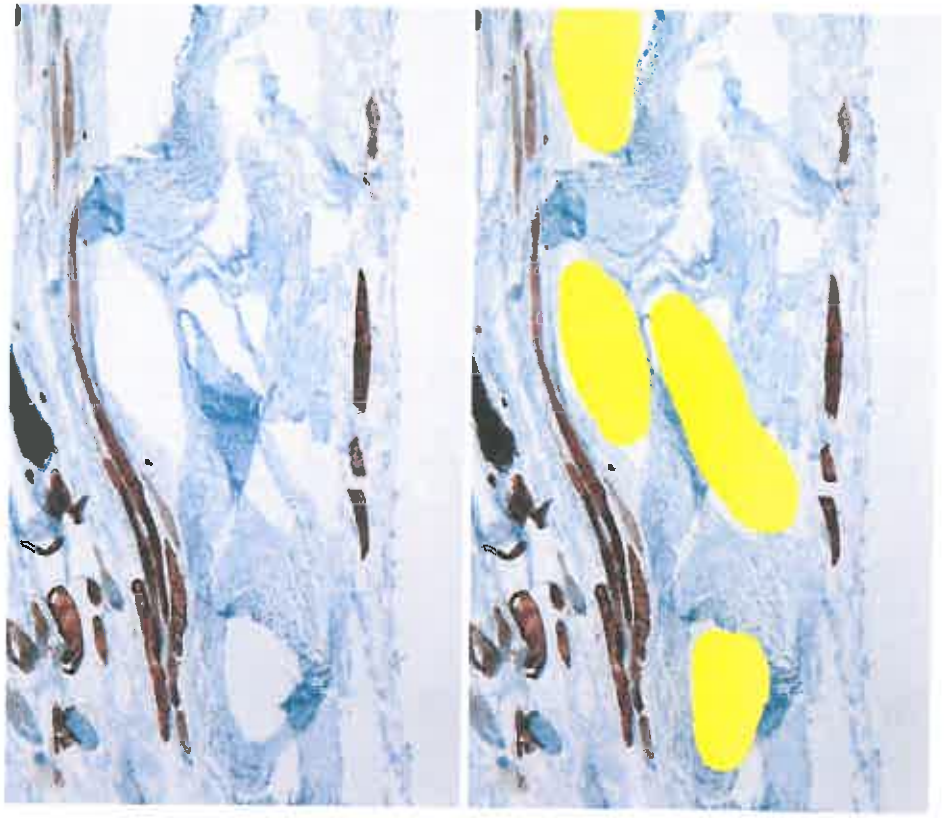


Figure set 7g.Involvement of striated muscle by the mesh, desmin stain, 10x.

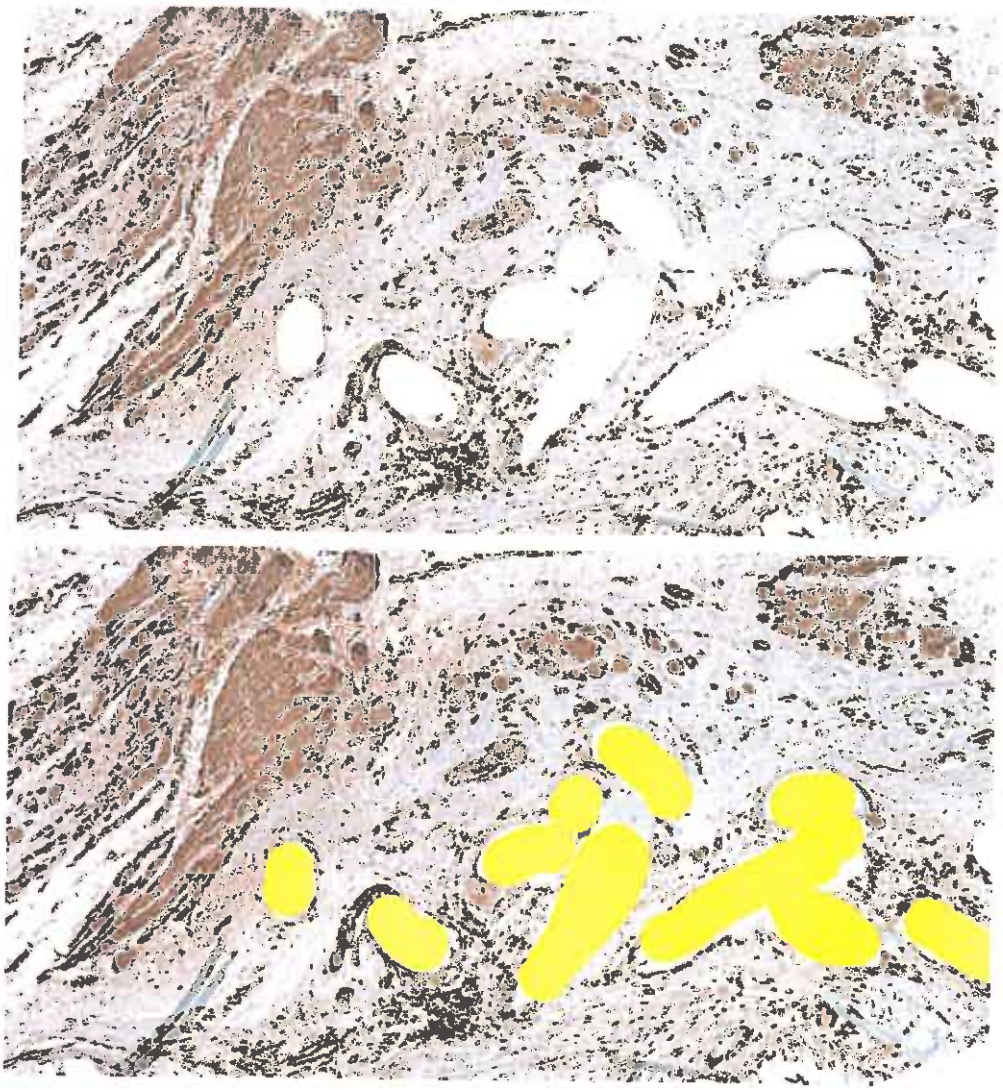


Figure set 8a.Involvement of the detrusor (bladder) muscle by the mesh, smooth muscle actin stain, 10x.

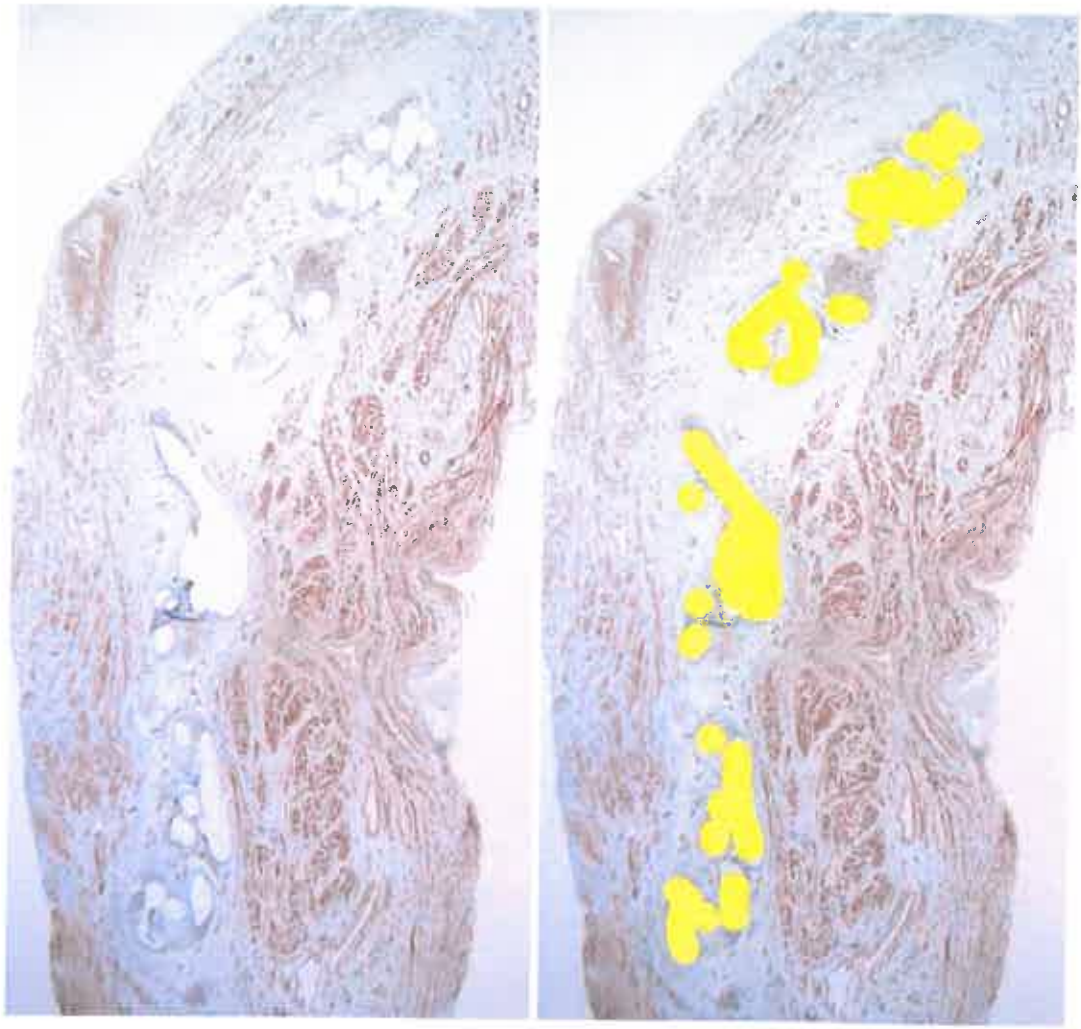


Figure set 8b.Involvement of smooth muscle by the mesh (thin strands of vaginal wall on the left of the mesh and thicker bundles of urethral muscles on the right), smooth muscle actin stain, 4x.

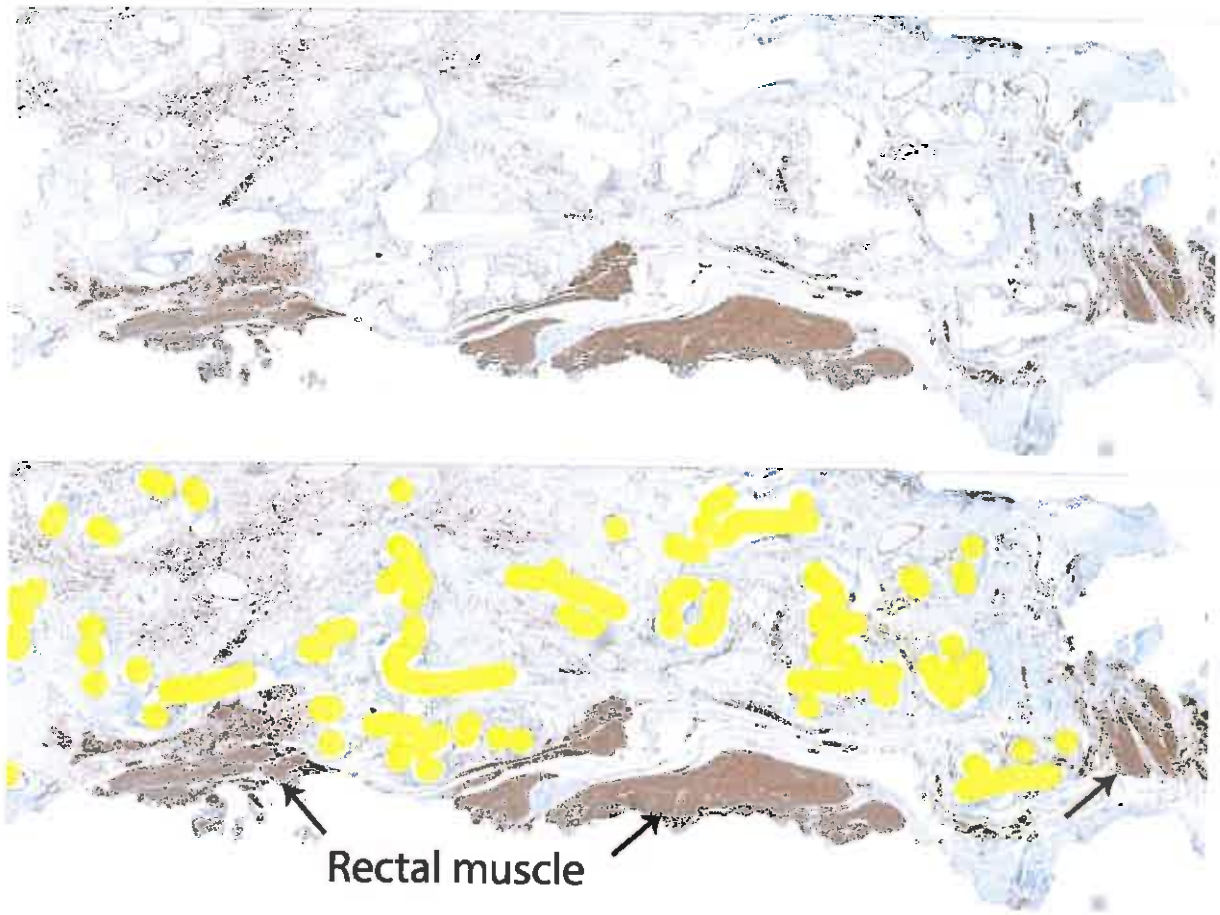


Figure set 8c. Involvement of the rectal muscle by the mesh, smooth muscle actin stain, 4x.

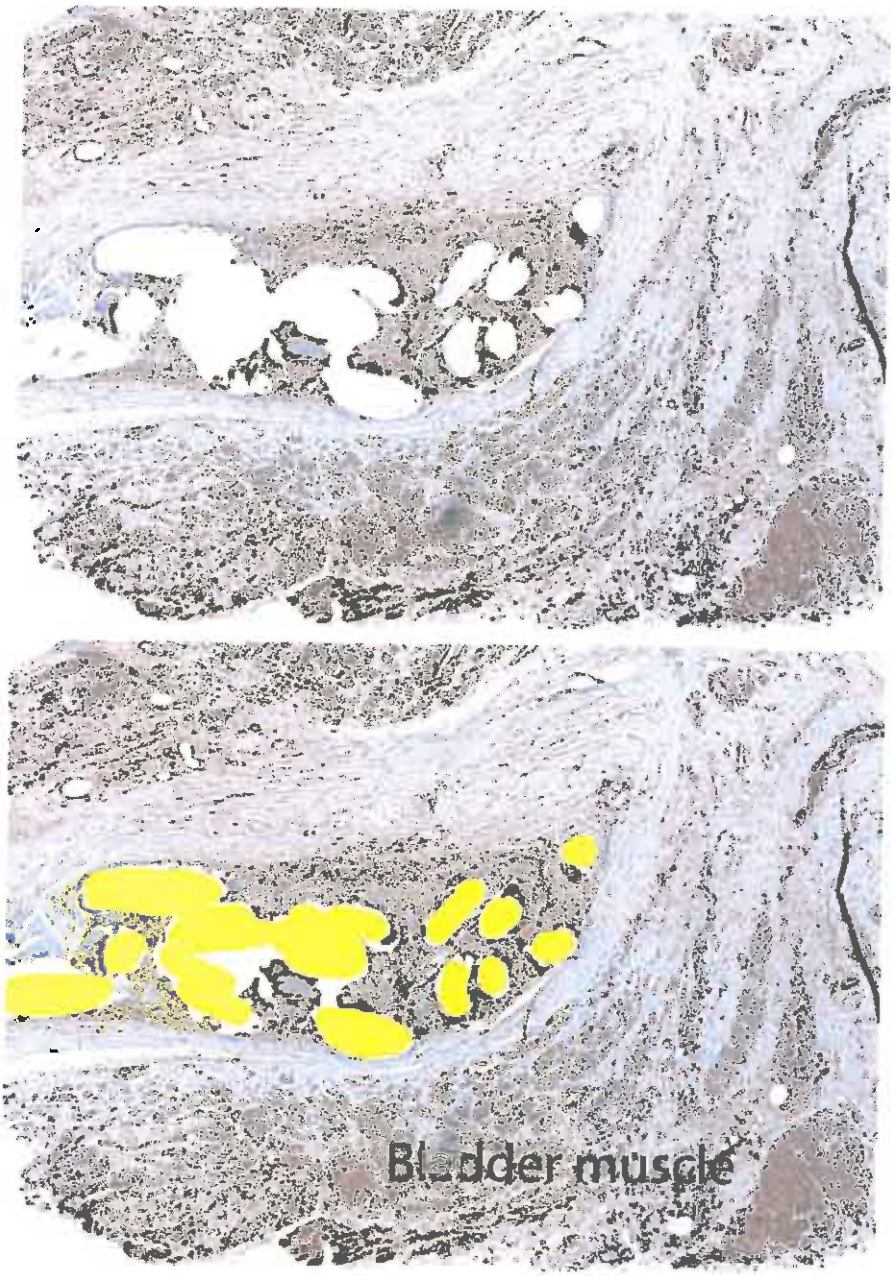


Figure set 8d.Involvement of the detrusor (bladder) muscle by the mesh, smooth muscle actin stain, 4x.

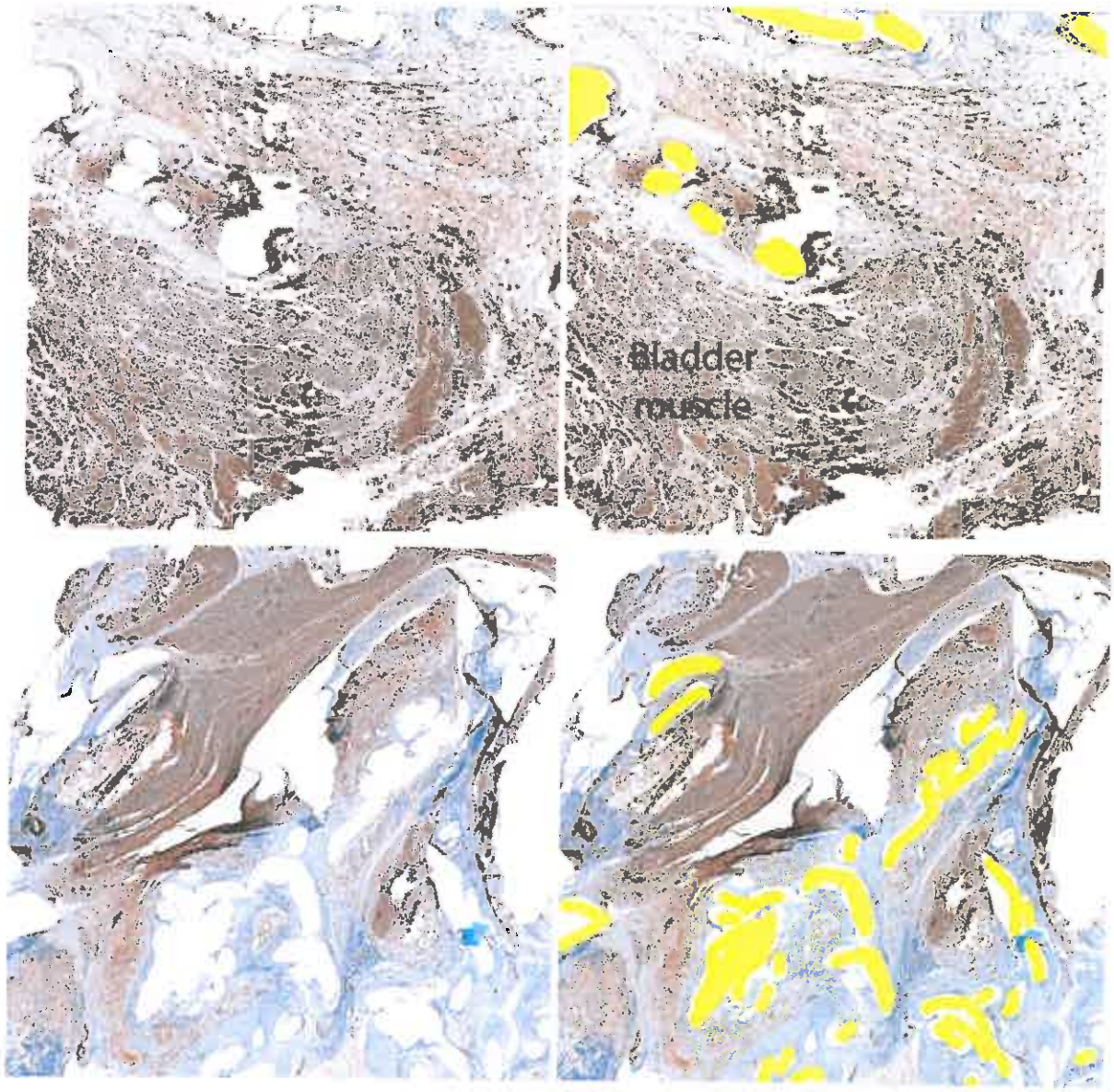


Figure set 8e.Involvement of the detrusor (bladder) muscle by the mesh, smooth muscle actin stain, 2.5x.

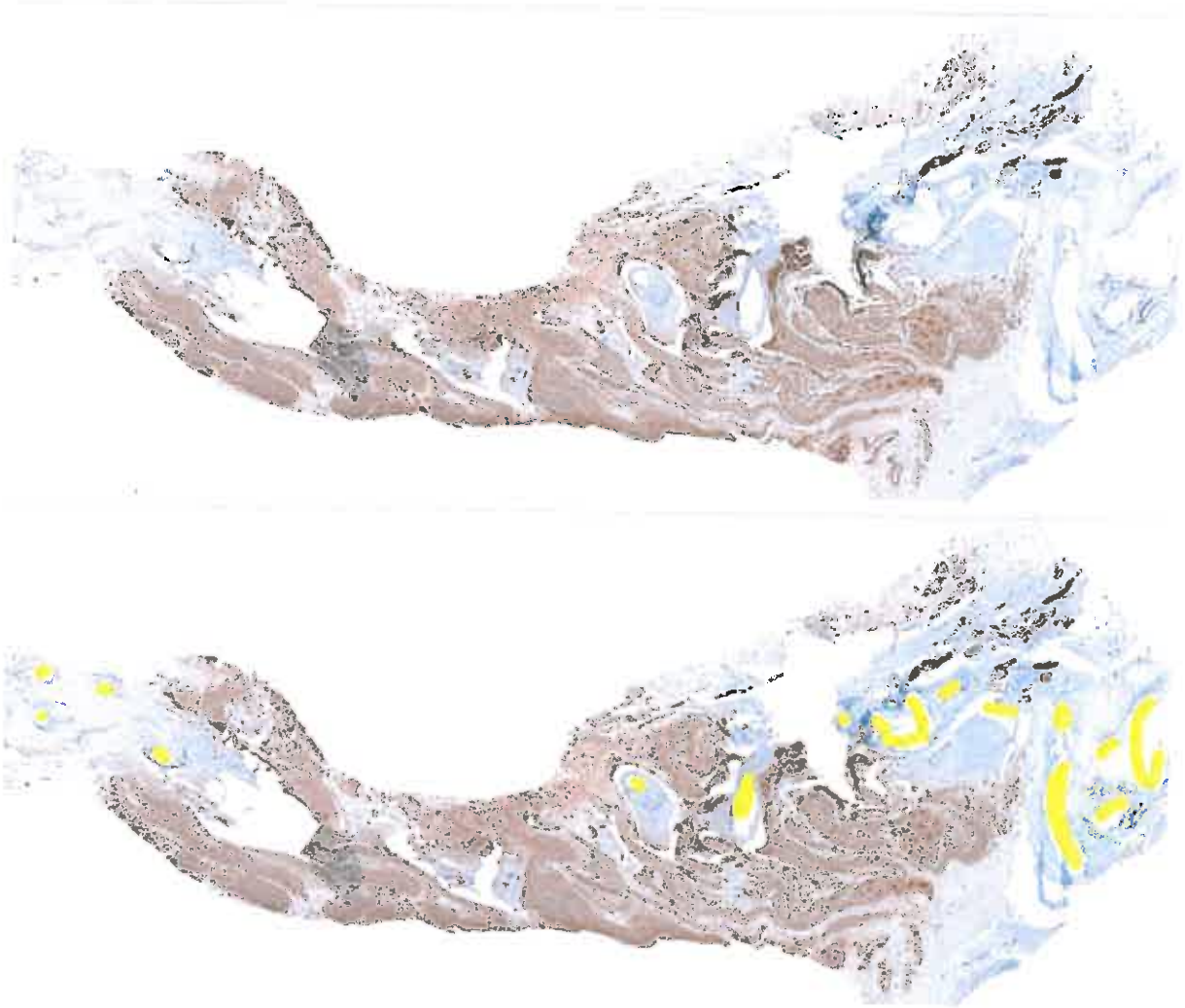


Figure set 8f.Involvement of the detrusor (bladder) muscle by the mesh, smooth muscle actin stain, 2.5x.

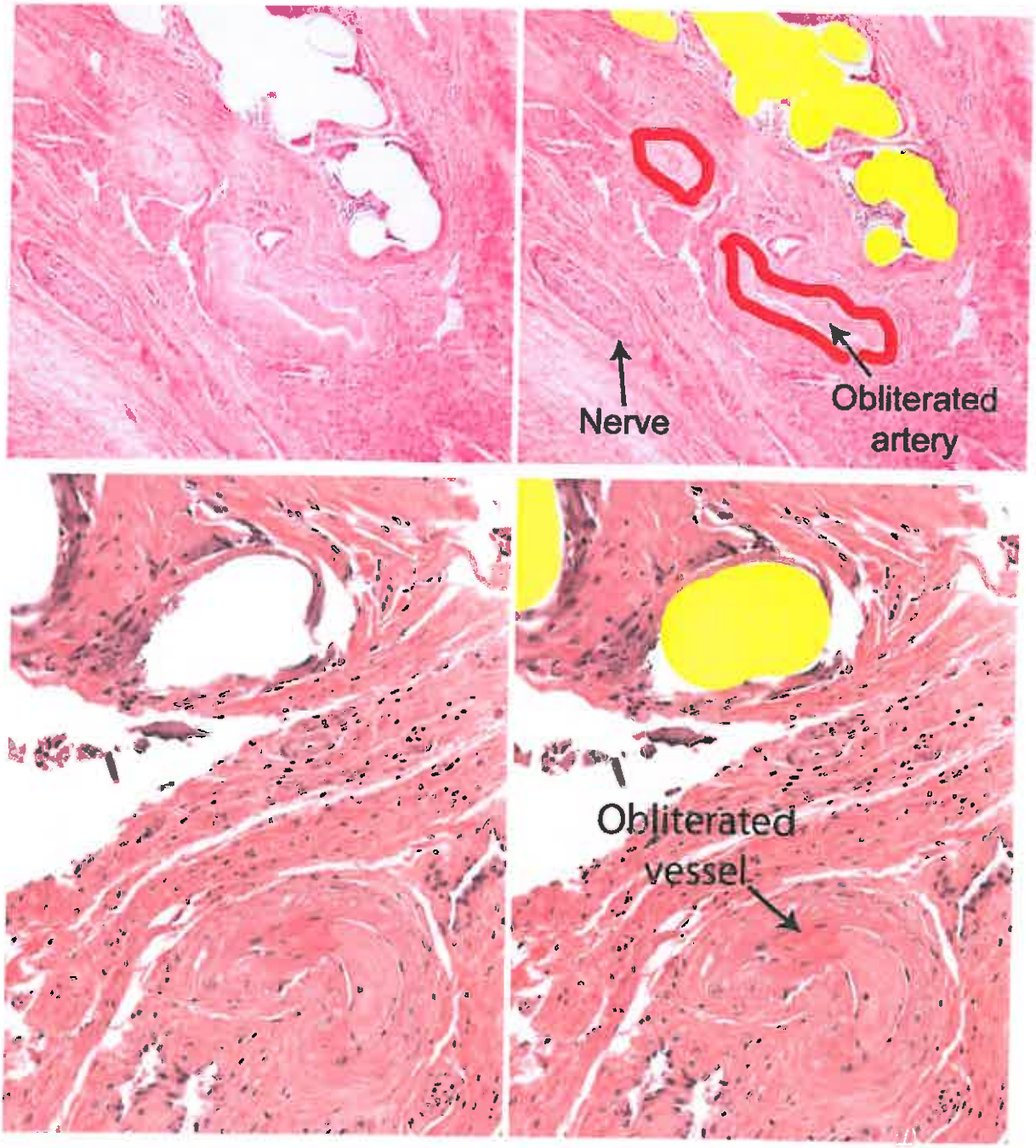


Figure set 9a.Arterial obliteration in the mesh-scar plate, H&E, 4x and 10x.

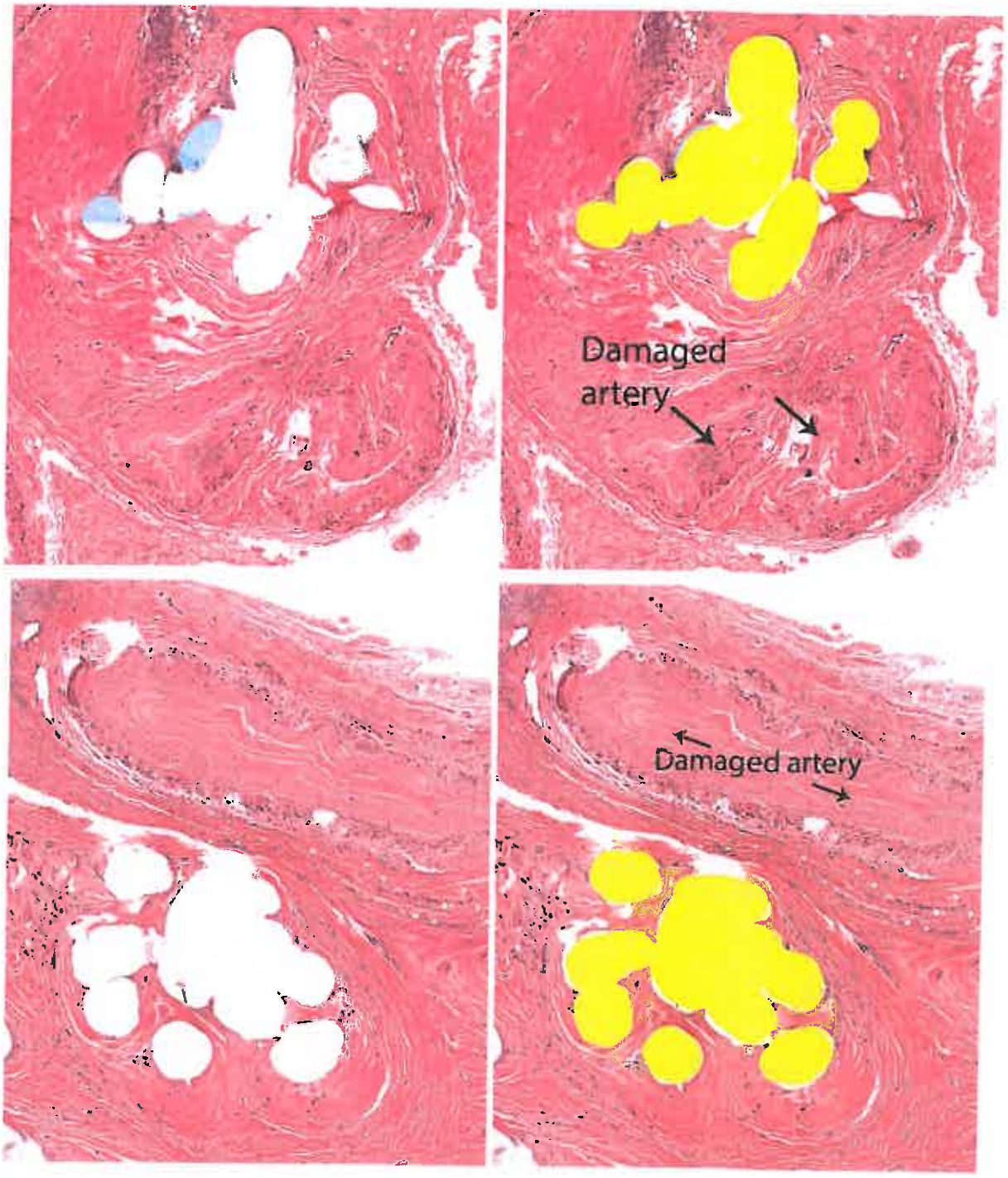


Figure set 9b.Arterial obliteration in the mesh-scar plate, H&E, 4x.

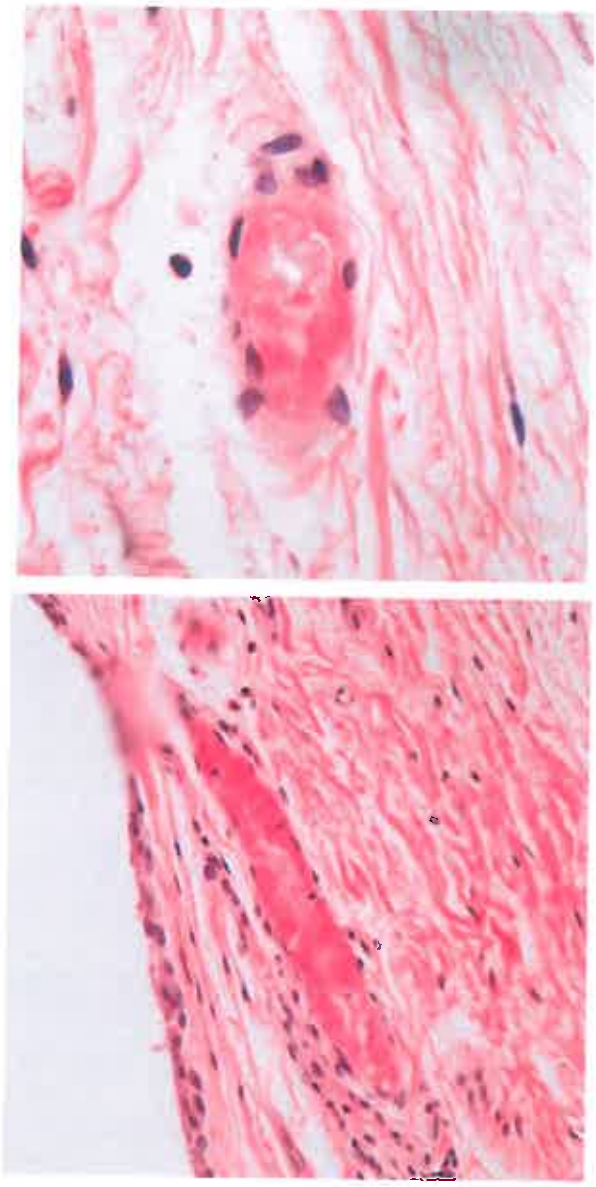


Figure set 9b.Examples of capillary thrombosis in the mesh-scar plate, H&E, 40x.

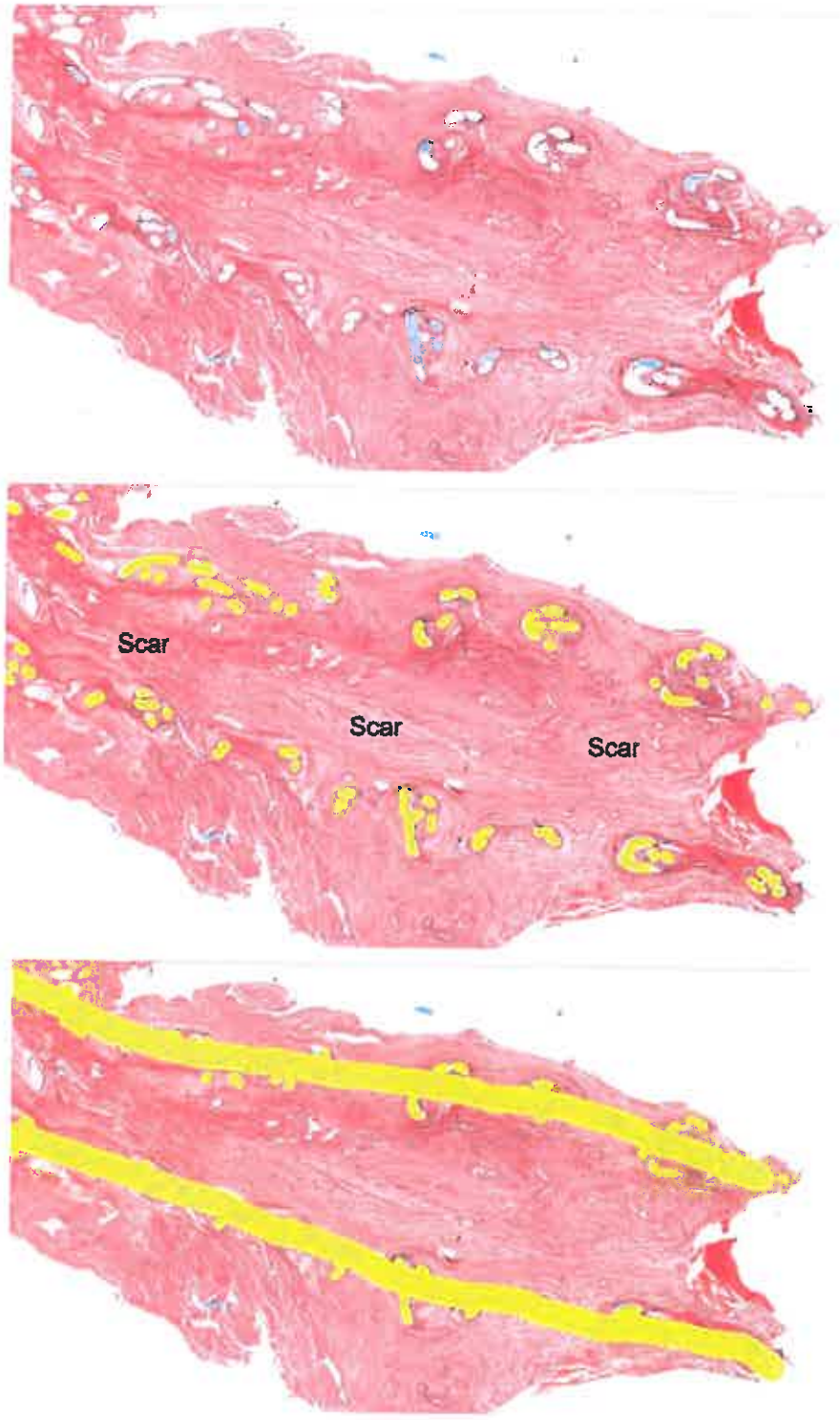


Figure set 10a.TVT sling curled into a roll, cross-sectioned through the parallel walls, H&E, 2.5x.

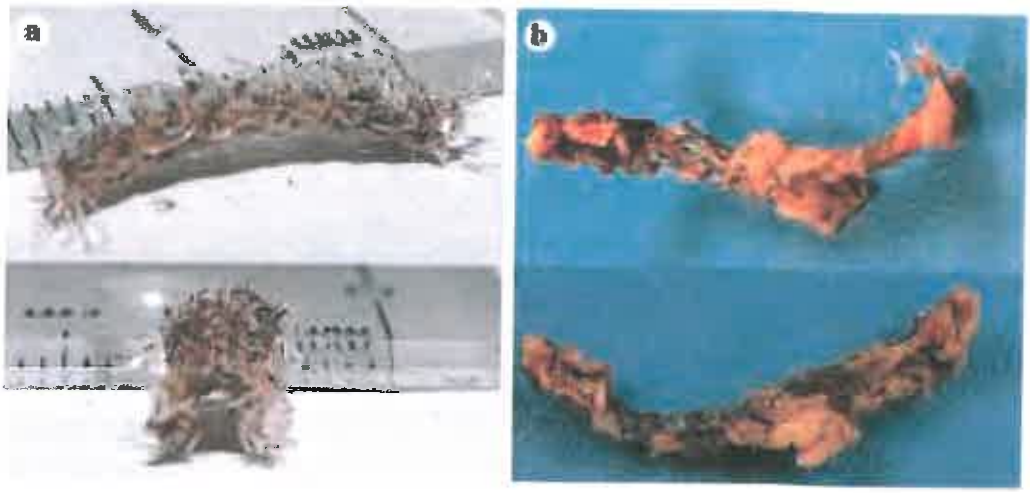


Figure set 10b.A TVT sling with curled edges (right sling is TVT), [557]

"Curling of the edges of explanted sling materials. ***a*** *| Segment of a sling, which was explanted with very little adherent tissue and a structure that is readily visible.* ***b*** *| Segment of a mesh sling, which was excised with adherent tissue remaining attached to the sling material."*

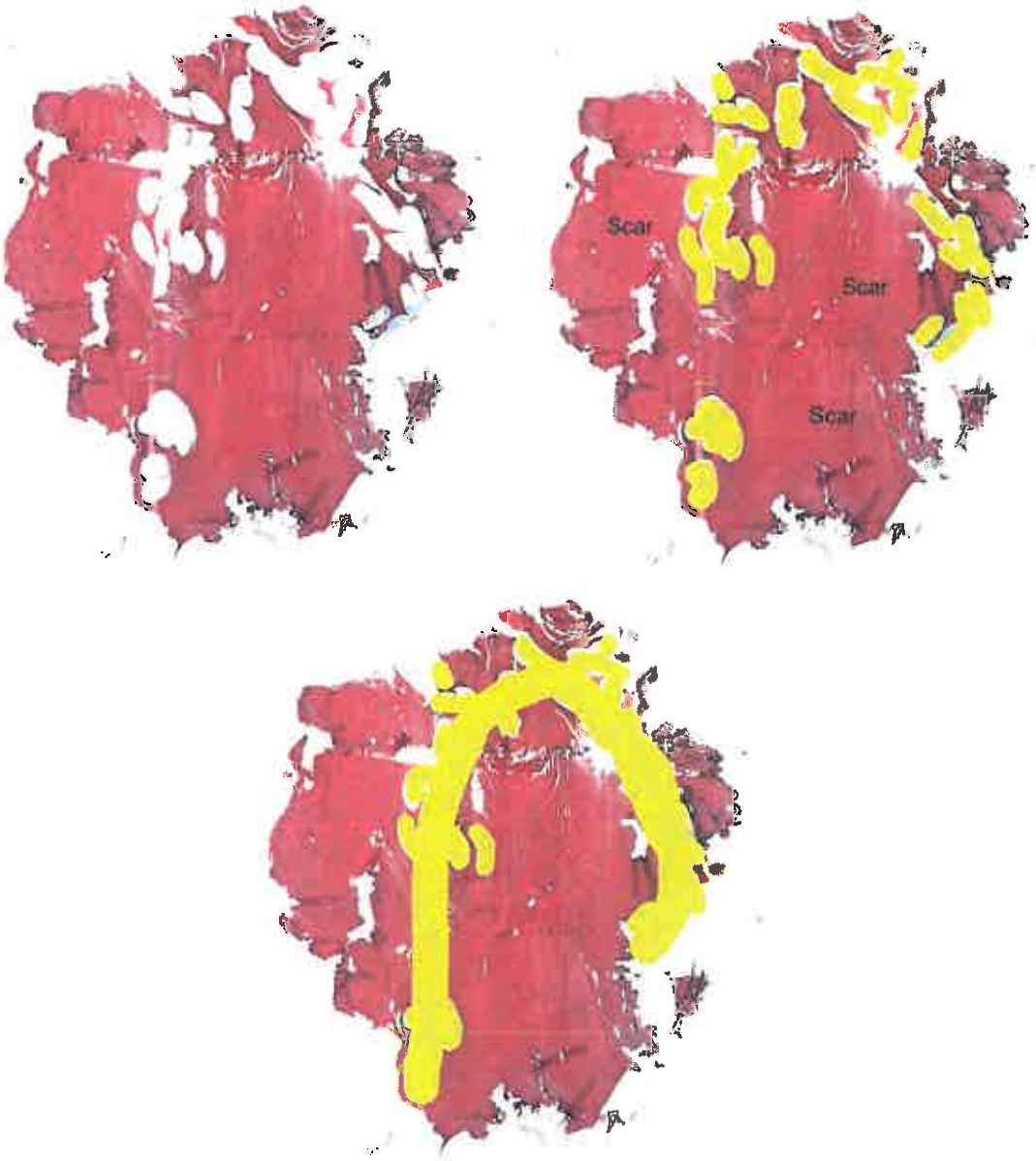


Figure set 10c. A TVT sling with curled edges, H&E, 2.5x.

Figure set 10d. A folded pelvic organ prolapse device, H&E, 1.6x.

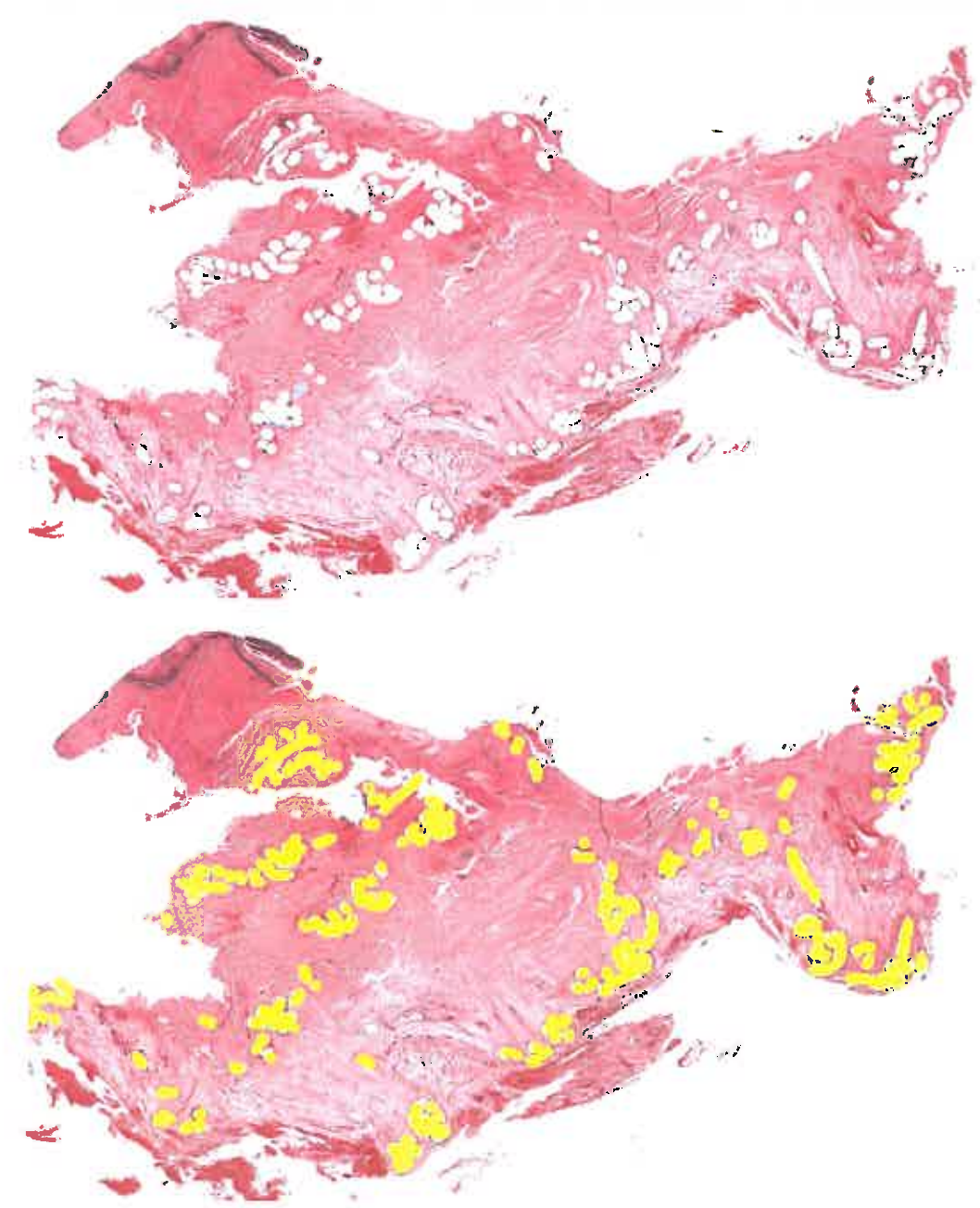


Figure set 10e. Complex folding of a Prolift pelvic organ prolapse device, H&E, 1.6x.

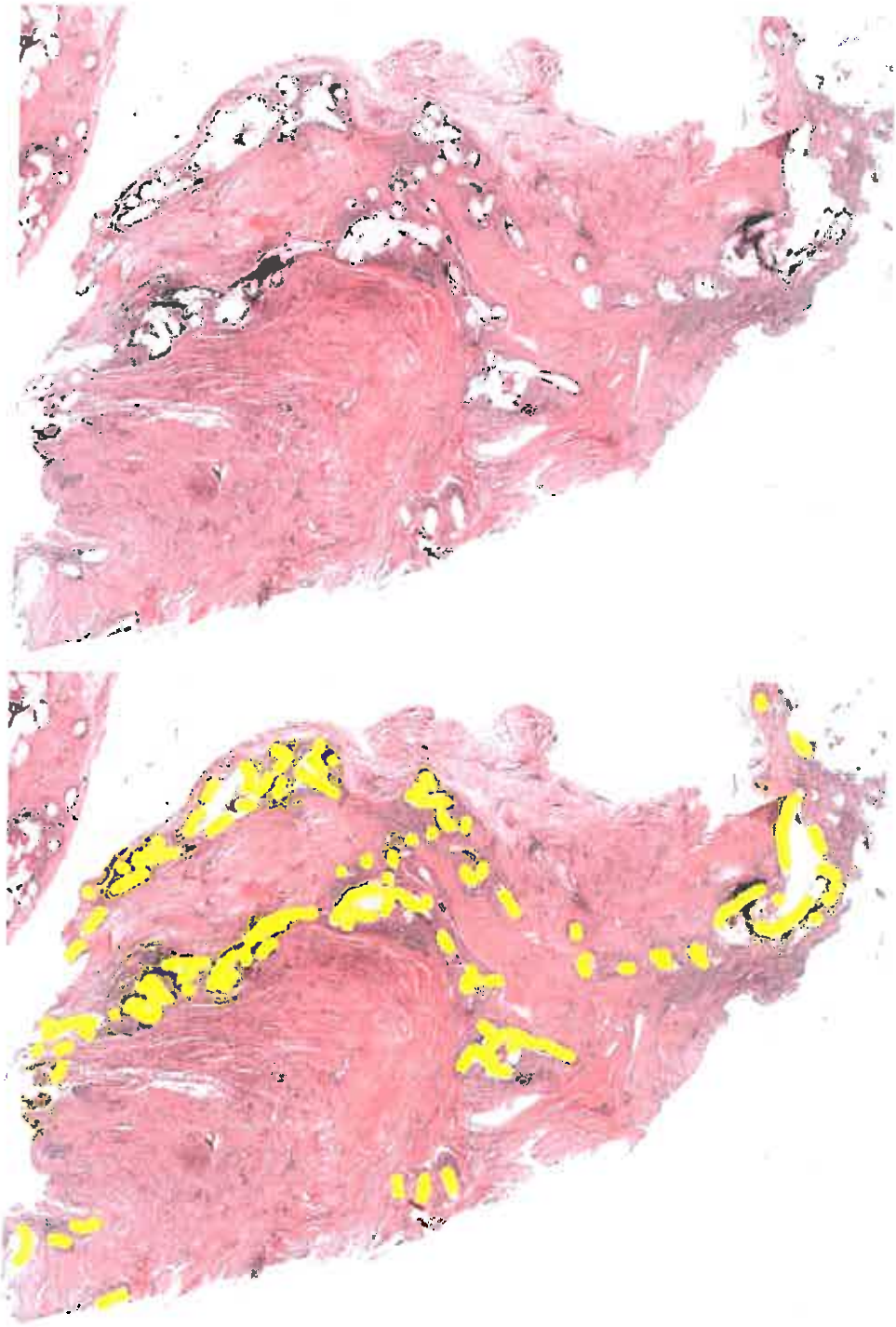


Figure set 10f. Complex folding of an exposed pelvic organ prolapse device, H&E, 1.6x.

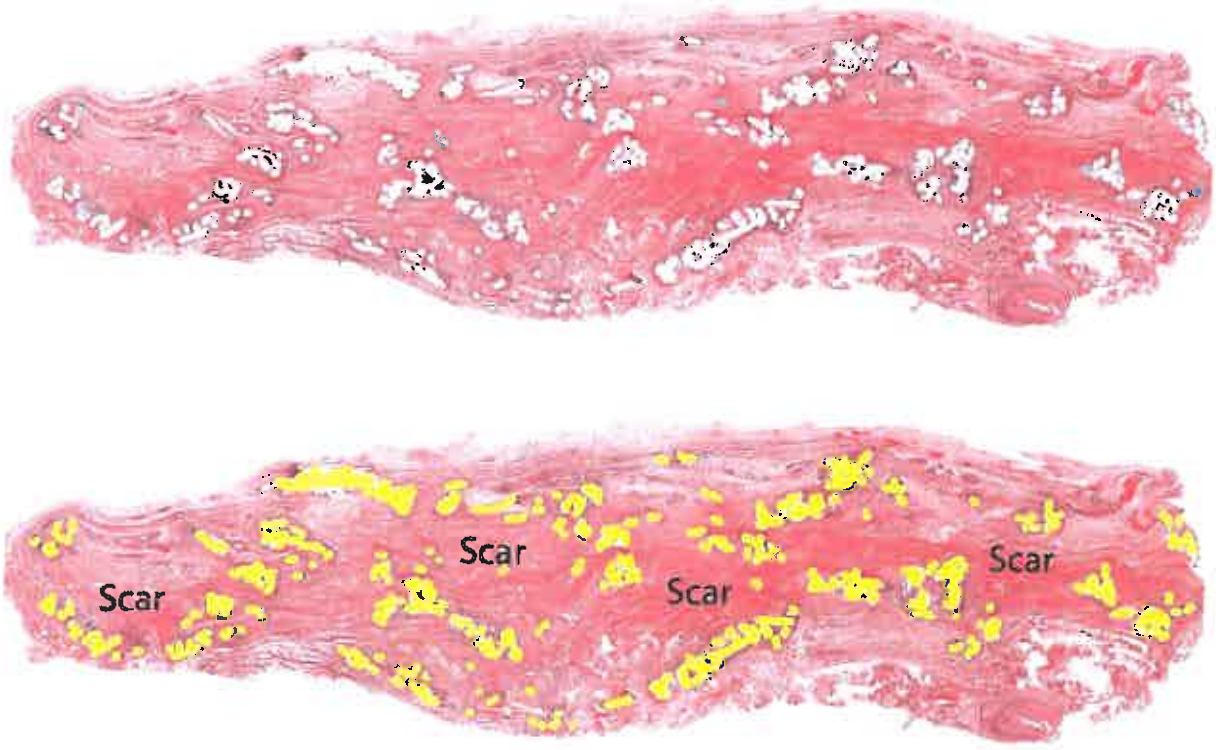


Figure set 10g. Complex folding of a Prolift pelvic organ prolapse device, H&E, 1.6x.

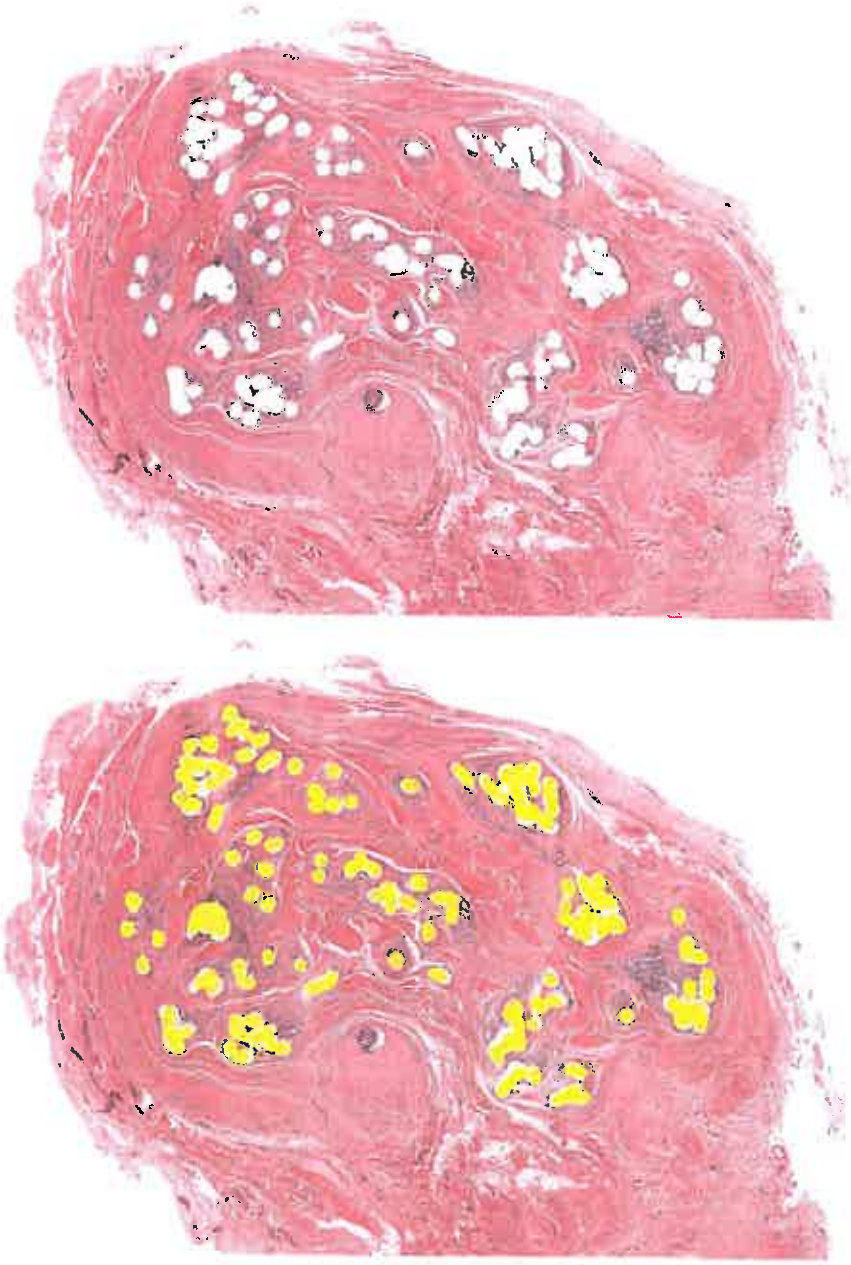


Figure set 10h. Complex folding of an arm of a Prolift pelvic organ prolapse device, H&E, 1.6x.

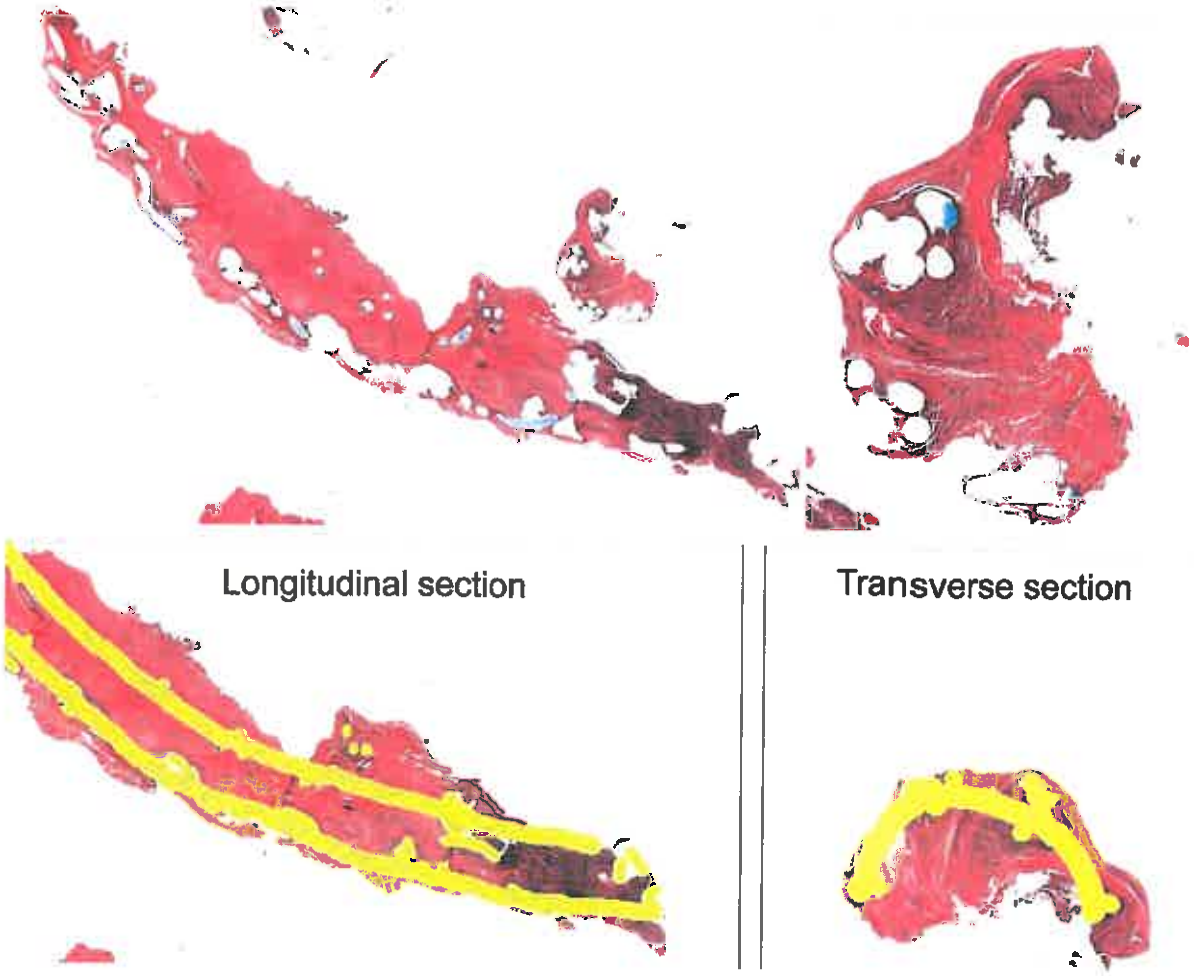


Figure set 11a. A TVT sling with an exposed curled edge, H&E, 2.5x.

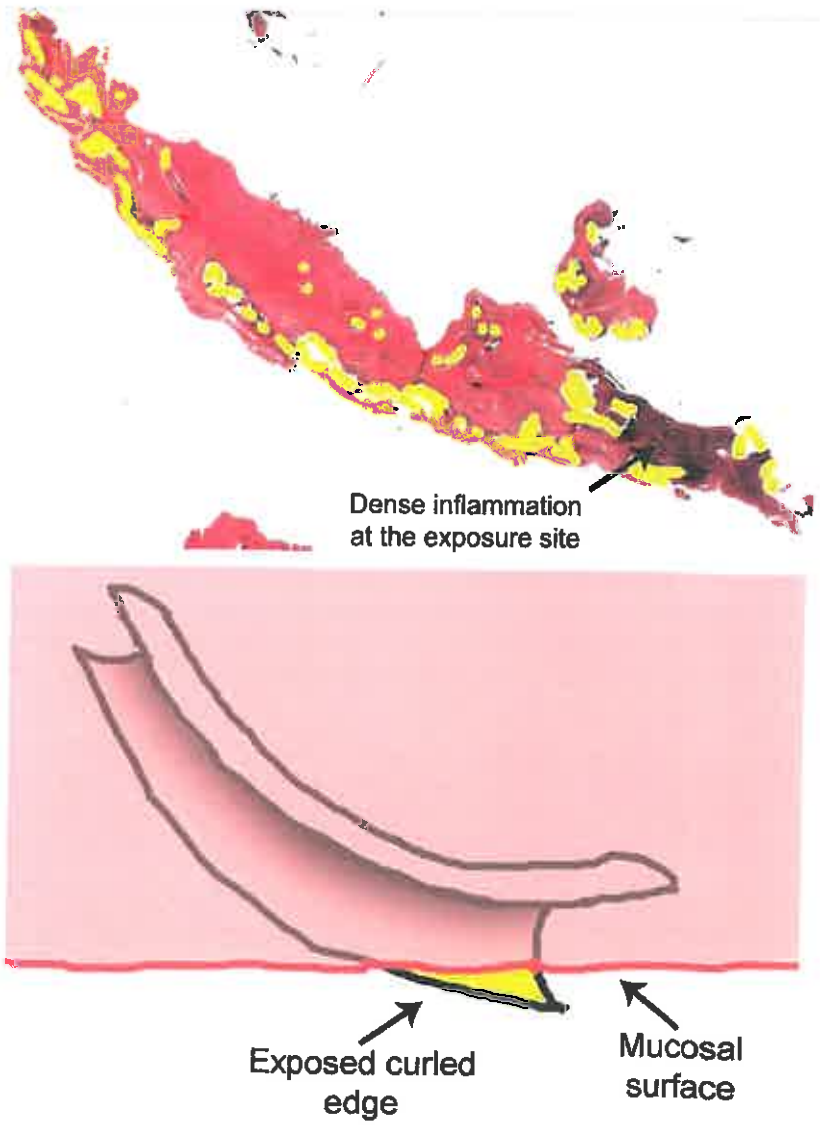


Figure set 11b. A cartoon showing the position of the exposed edge from Figure 11a.

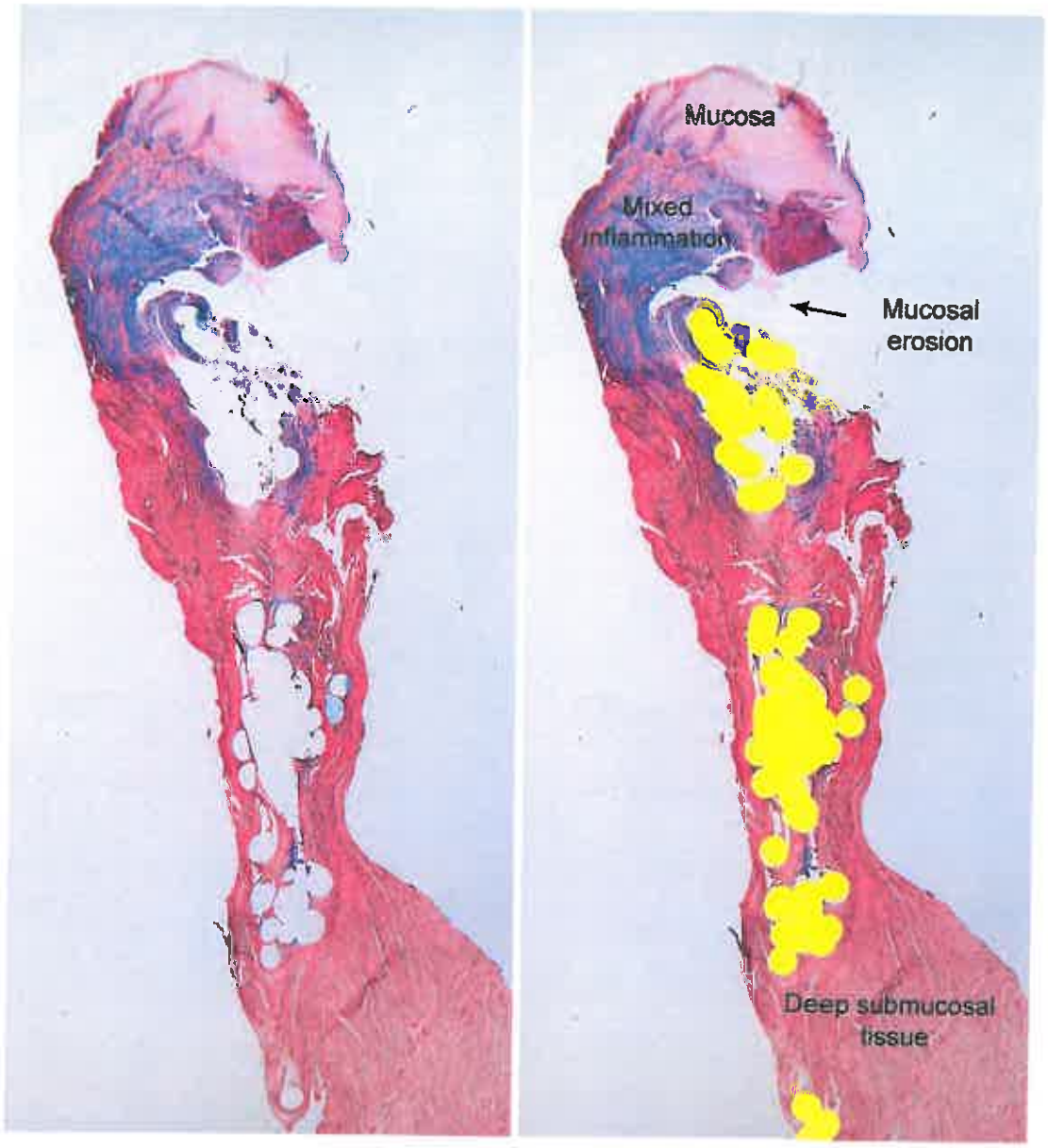


Figure set 11c.An exposed edge of TVT sling rotated towards the mucosa, H&E, 2.5x.

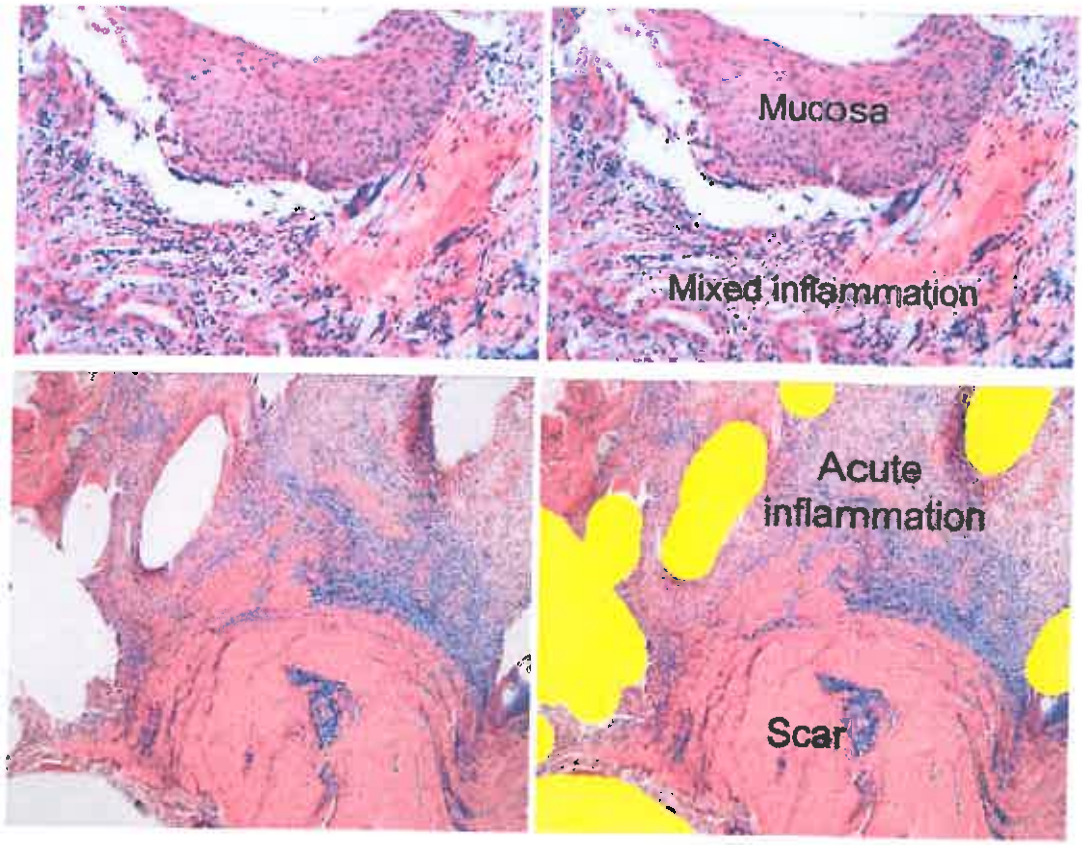


Figure set 12a.Acute inflammation at a site of TVT exposure, H&E, 2.5x.

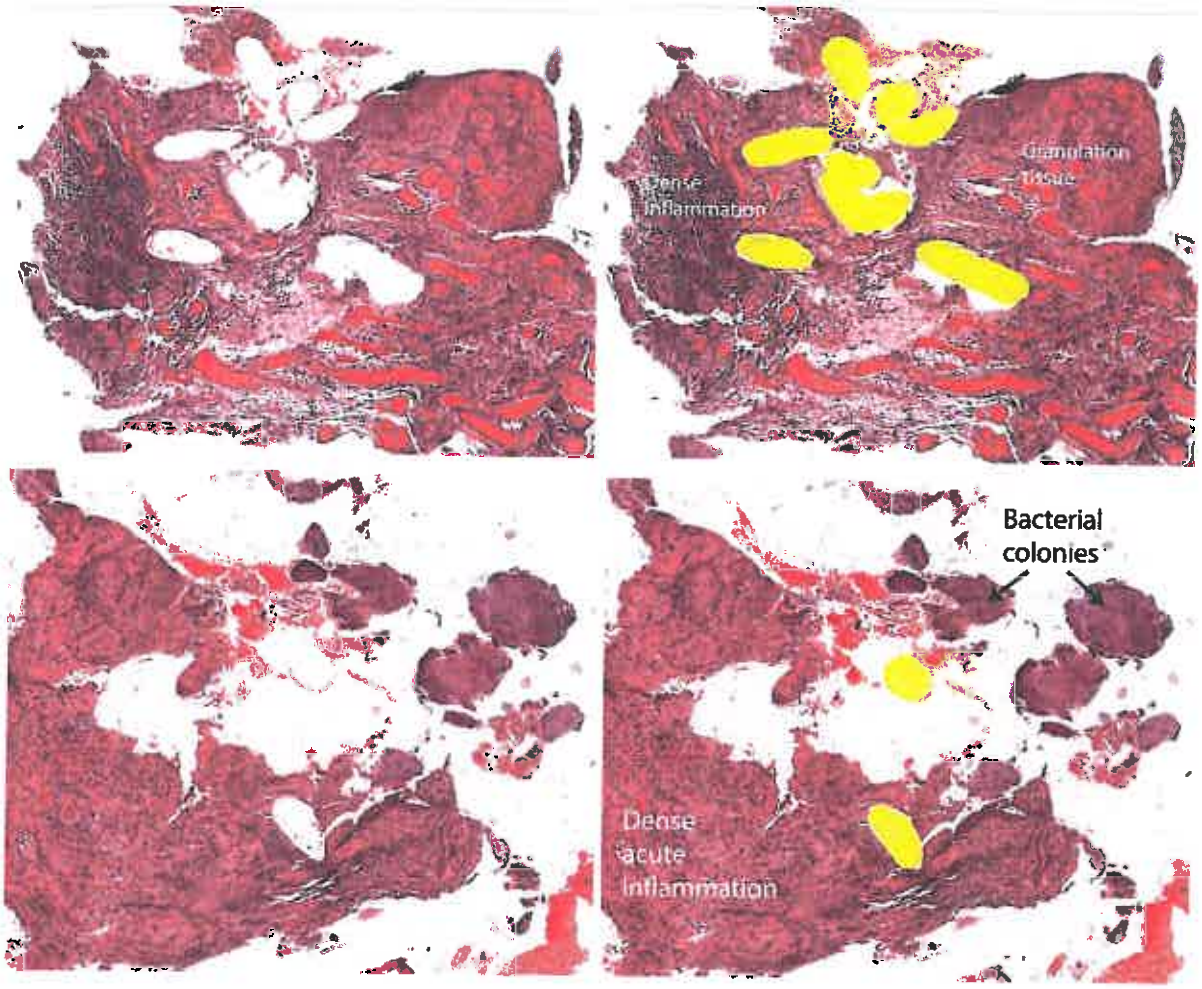


Figure set 12b.Granulation tissue, cute inflammation and bacterial colonies at a site of Gynecare mesh exposure, H&E, 2.5x.

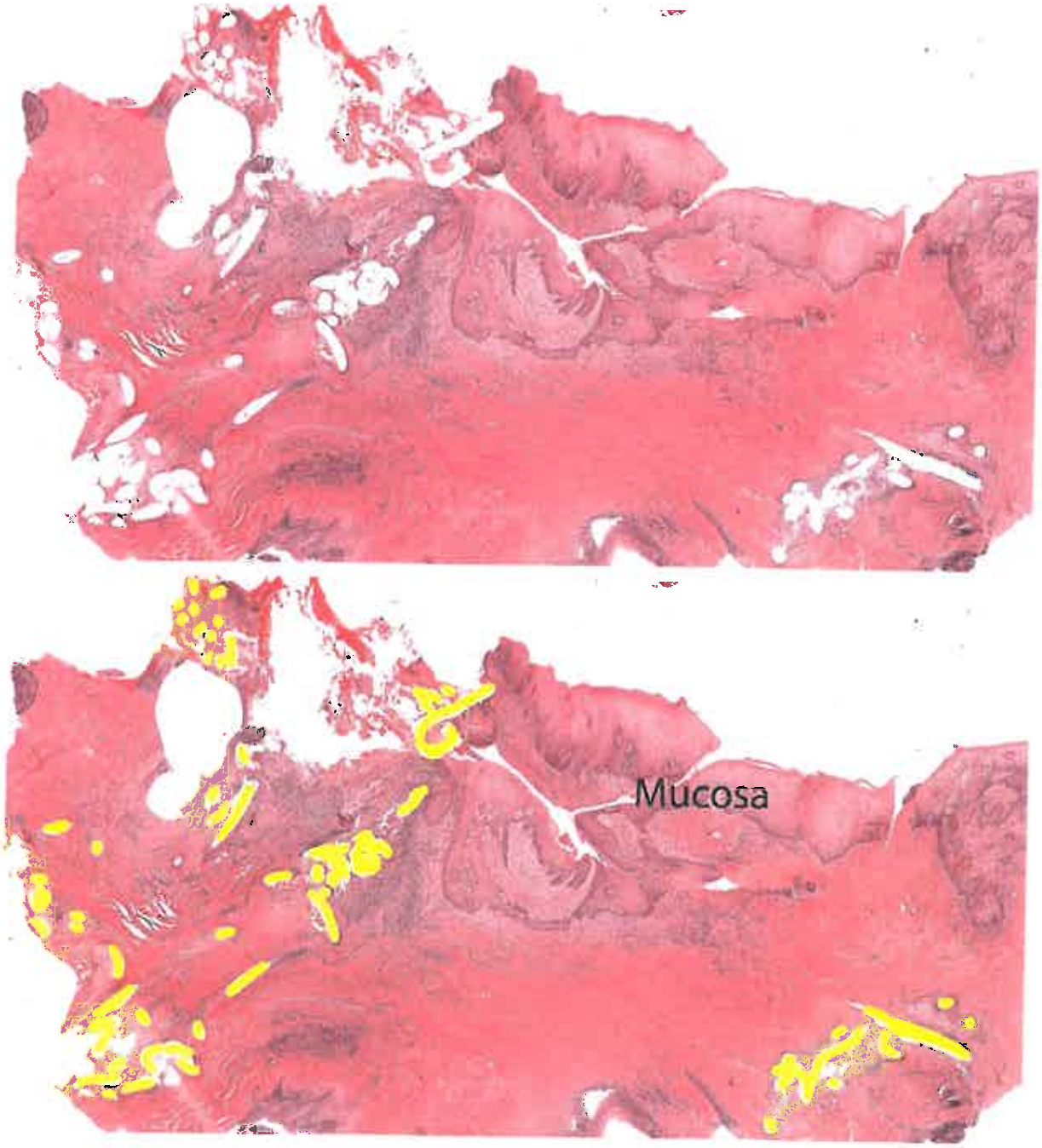


Figure set 12c. Mesh erosion through vaginal mucosa, H&E, 1.6x.

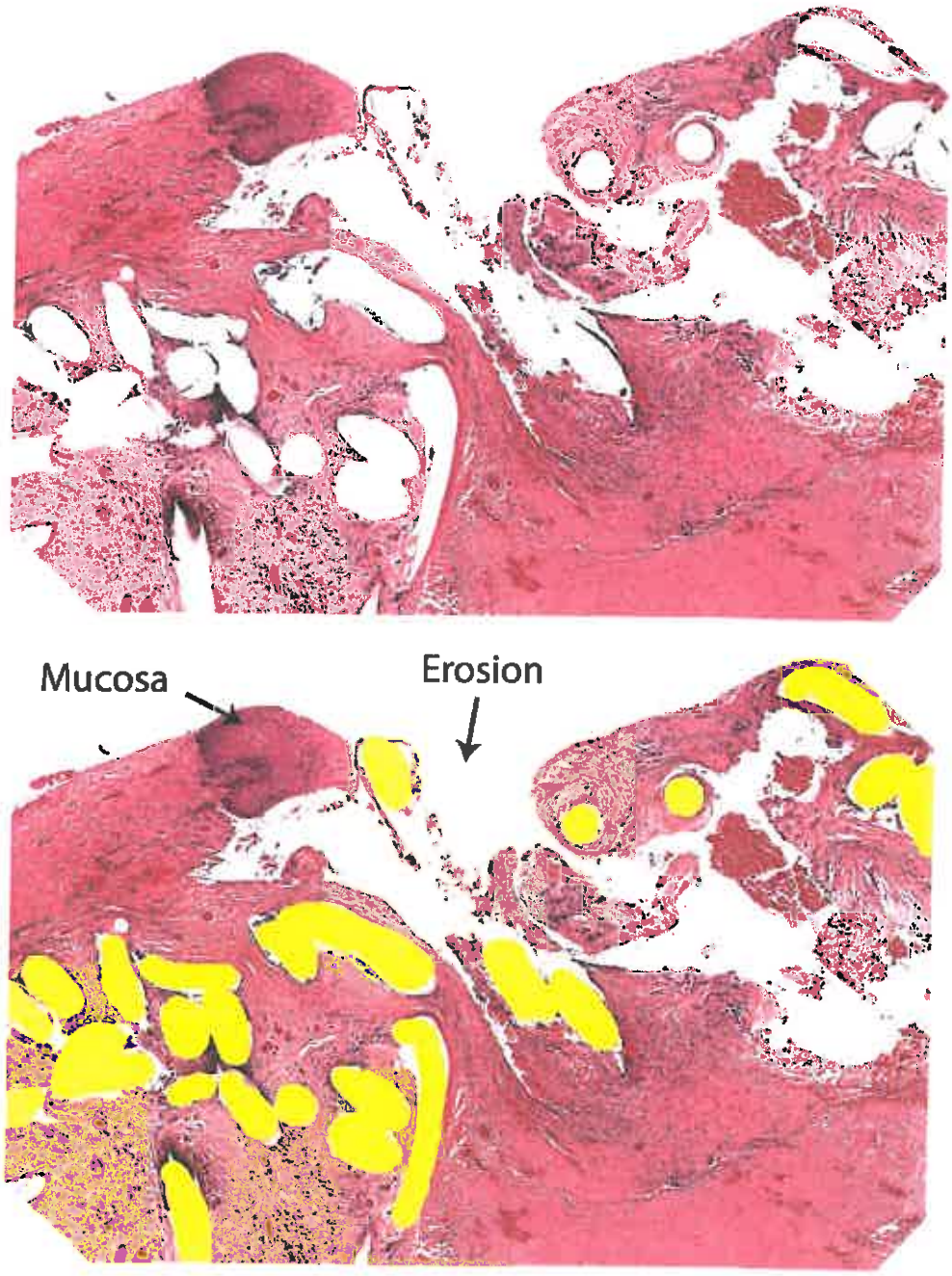


Figure set 12d. Mesh erosion through vaginal mucosa, H&E, 4x.

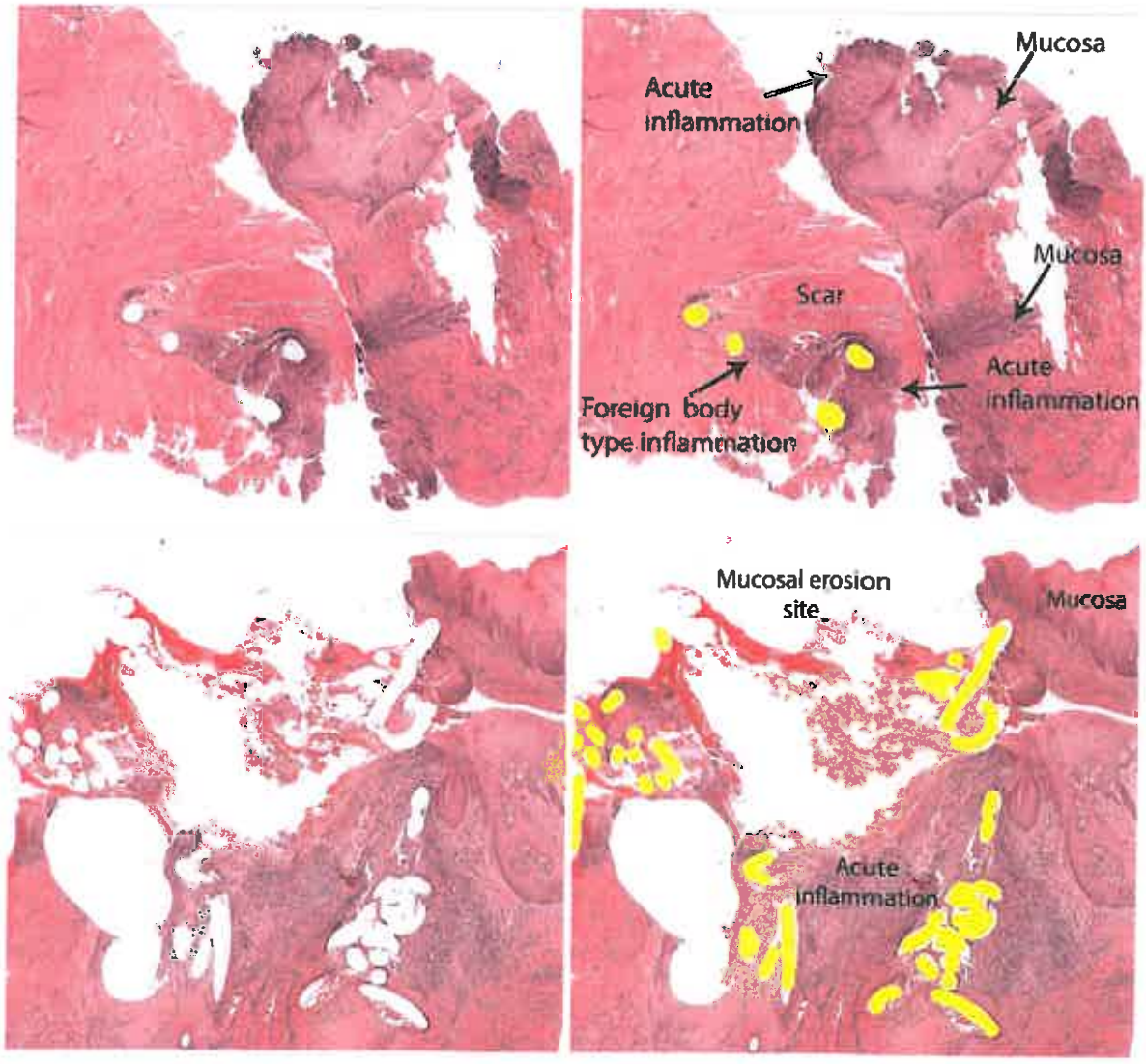


Figure set 12e. .Mesh erosion through vaginal mucosa, H&E, 1.6x.

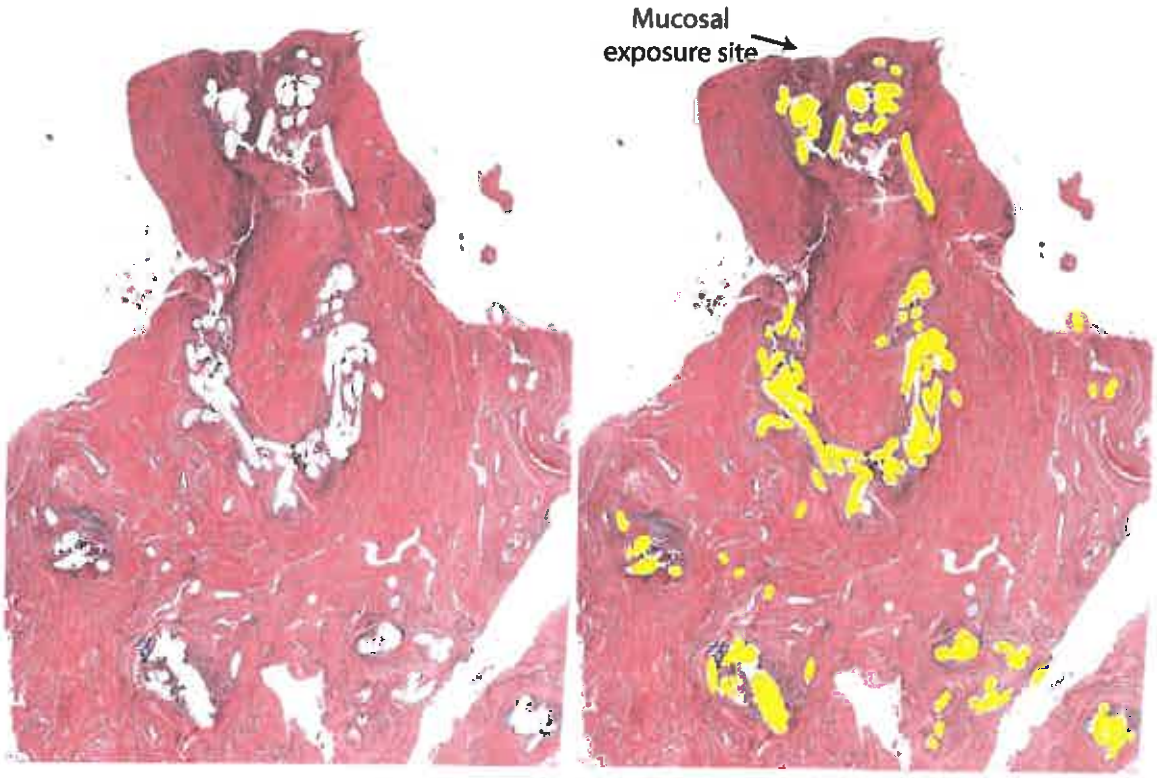


Figure set 12f. Mesh erosion through vaginal mucosa, H&E, 1.6x.

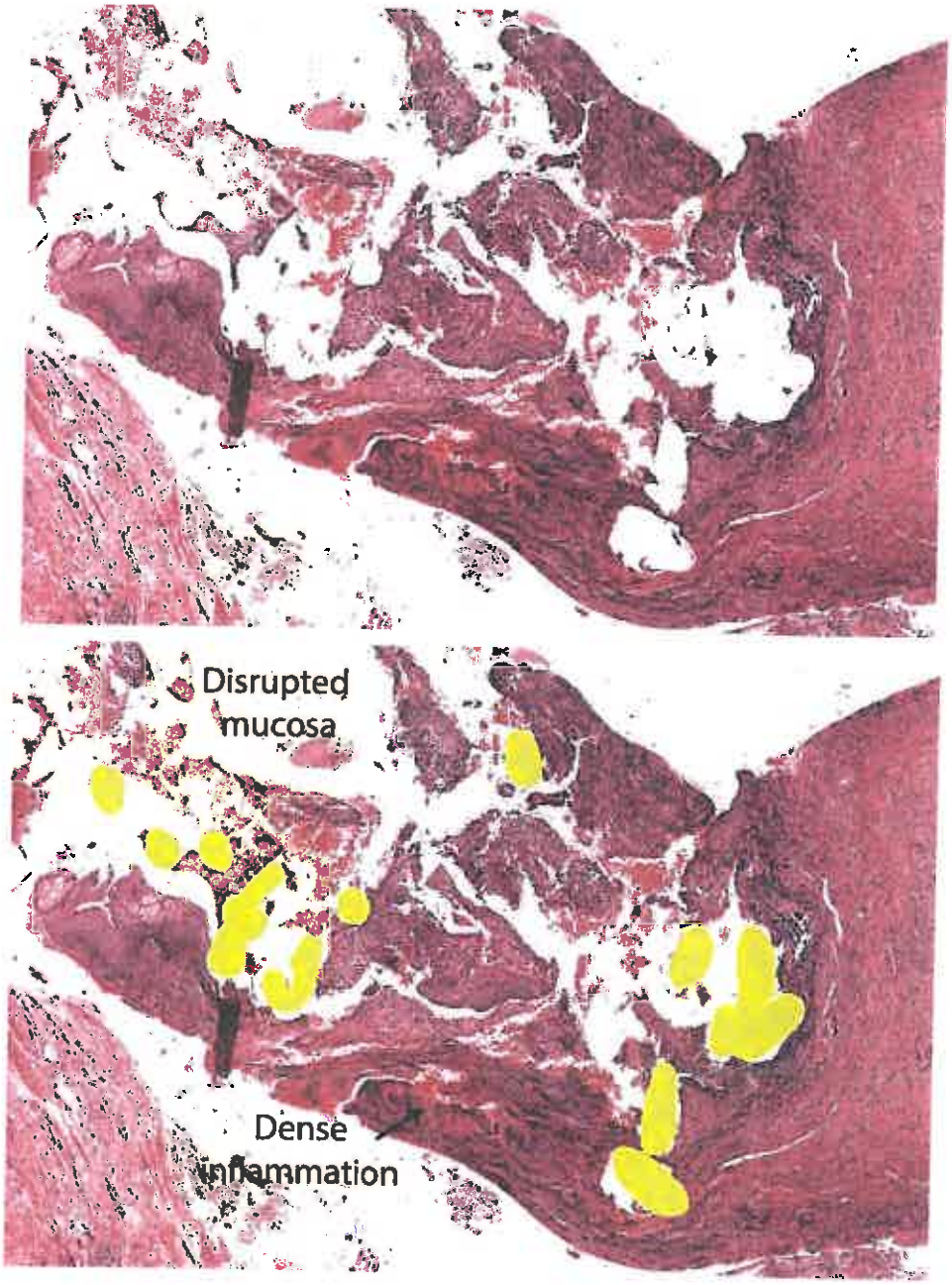


Figure set 12g. .Mesh erosion through vaginal mucosa, H&E, 1.6x.

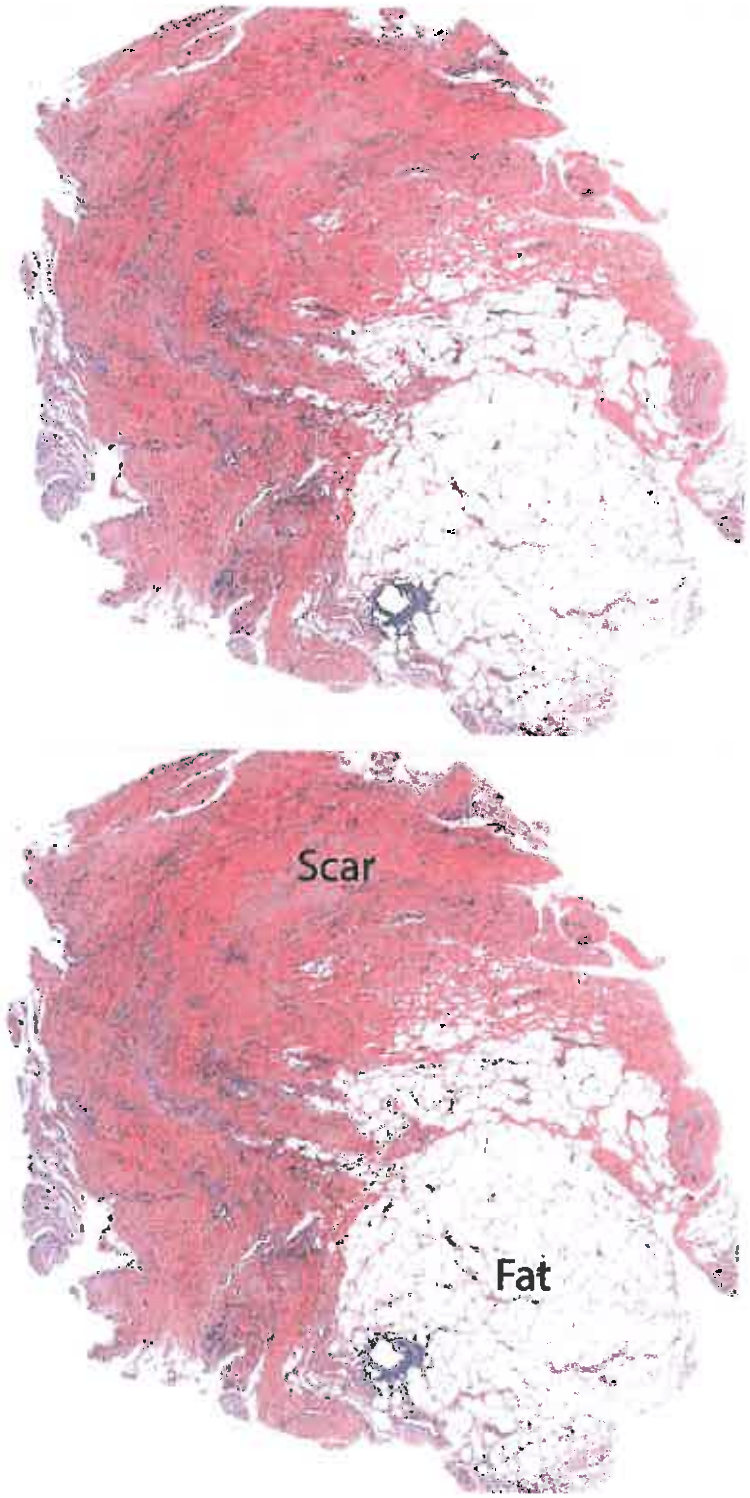


Figure set 12h. .Extension of inflammation and scarring from a mesh erosion site into the deep soft tissue, H&E, 1.6x.

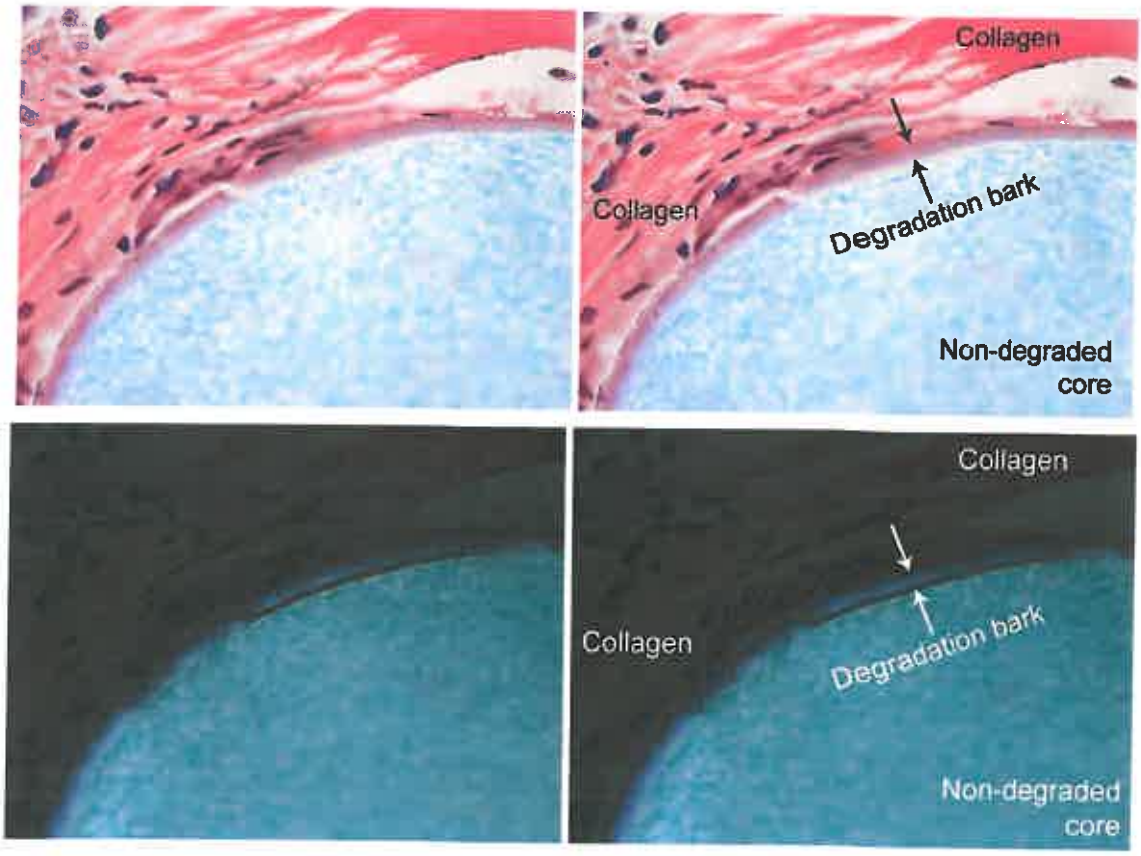


Figure set 13a.Polypropylene degradation layer in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x.

Note that collagen, one of the most refractile components of human tissue is much darker than polypropylene in polarized light.

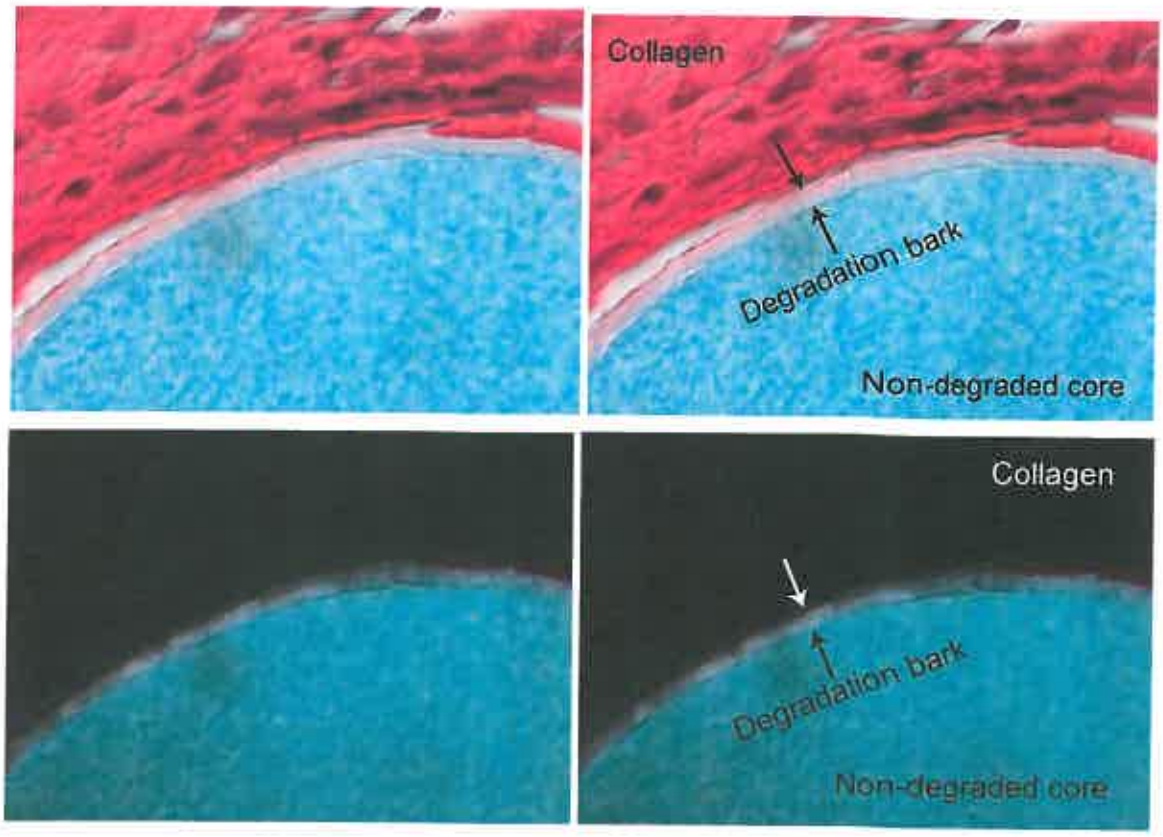


Figure set 13b.Polypropylene degradation layer in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x.

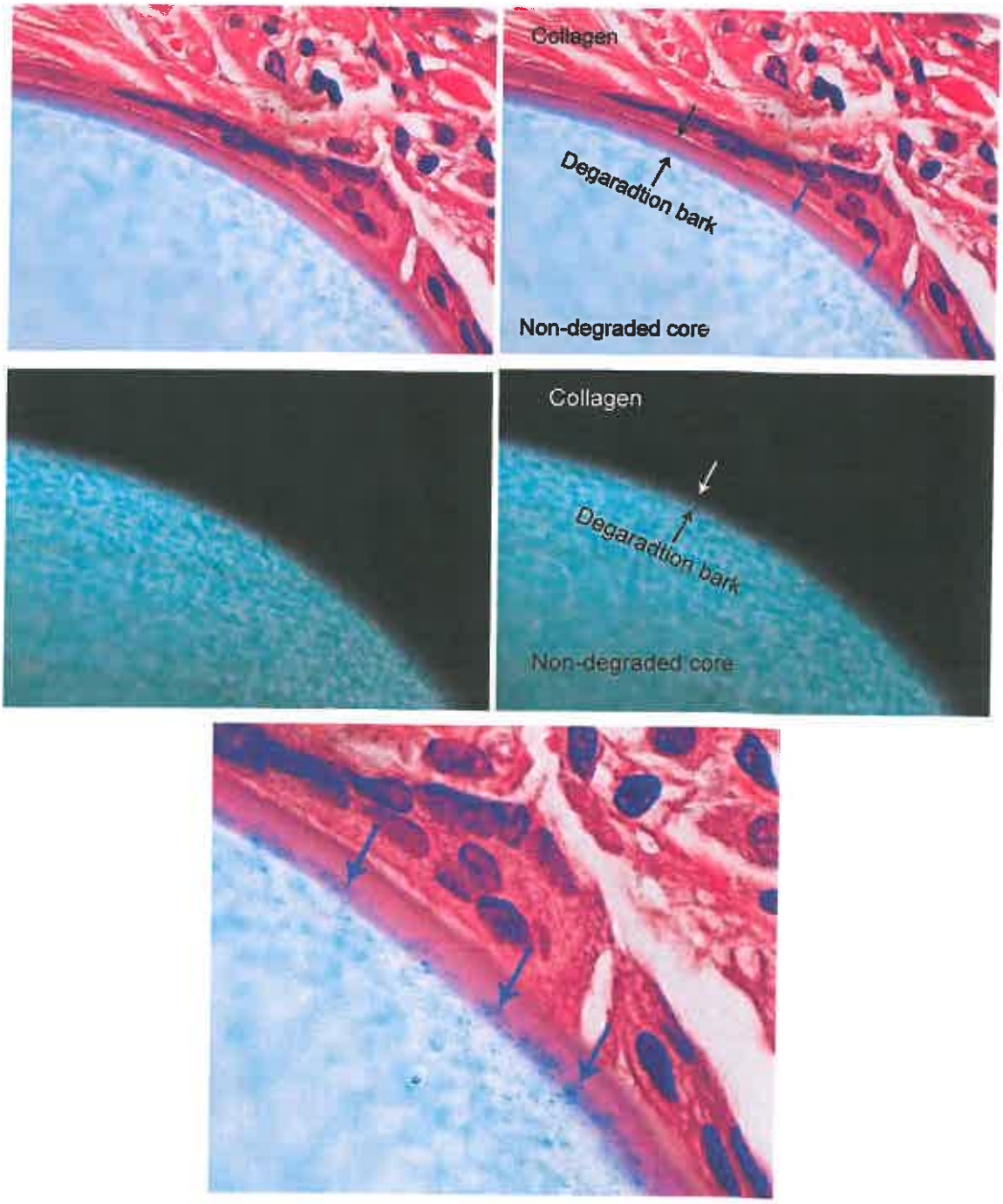


Figure set 13c.Polypropylene degradation layer in regular (upper panel) and the same field in polarized light (middle panel), H&E, 100x.

The mesh filament was manufactures with addition of blue dye granules. The granules are present in the degraded layer confirming its origin from polypropylene (lower panel).

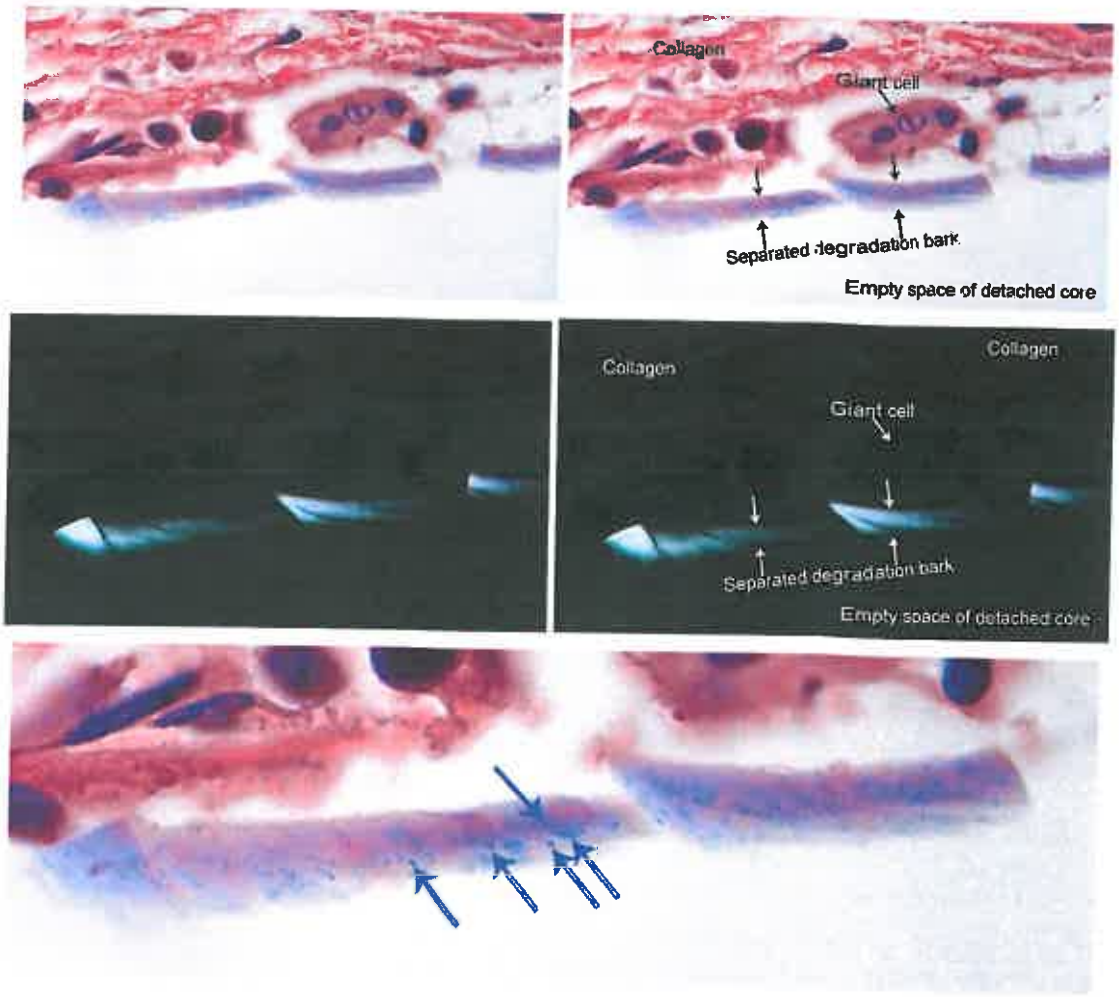


Figure set 13d.Polypropylene degradation layer in regular (upper panel) and the same field in polarized light (middle panel), enlargement is in the lower panel, H&E, 100x.
In this field the bark detached from the core and neither its birefringence nor presence of the blue granules can be explained by an overlap with the core.

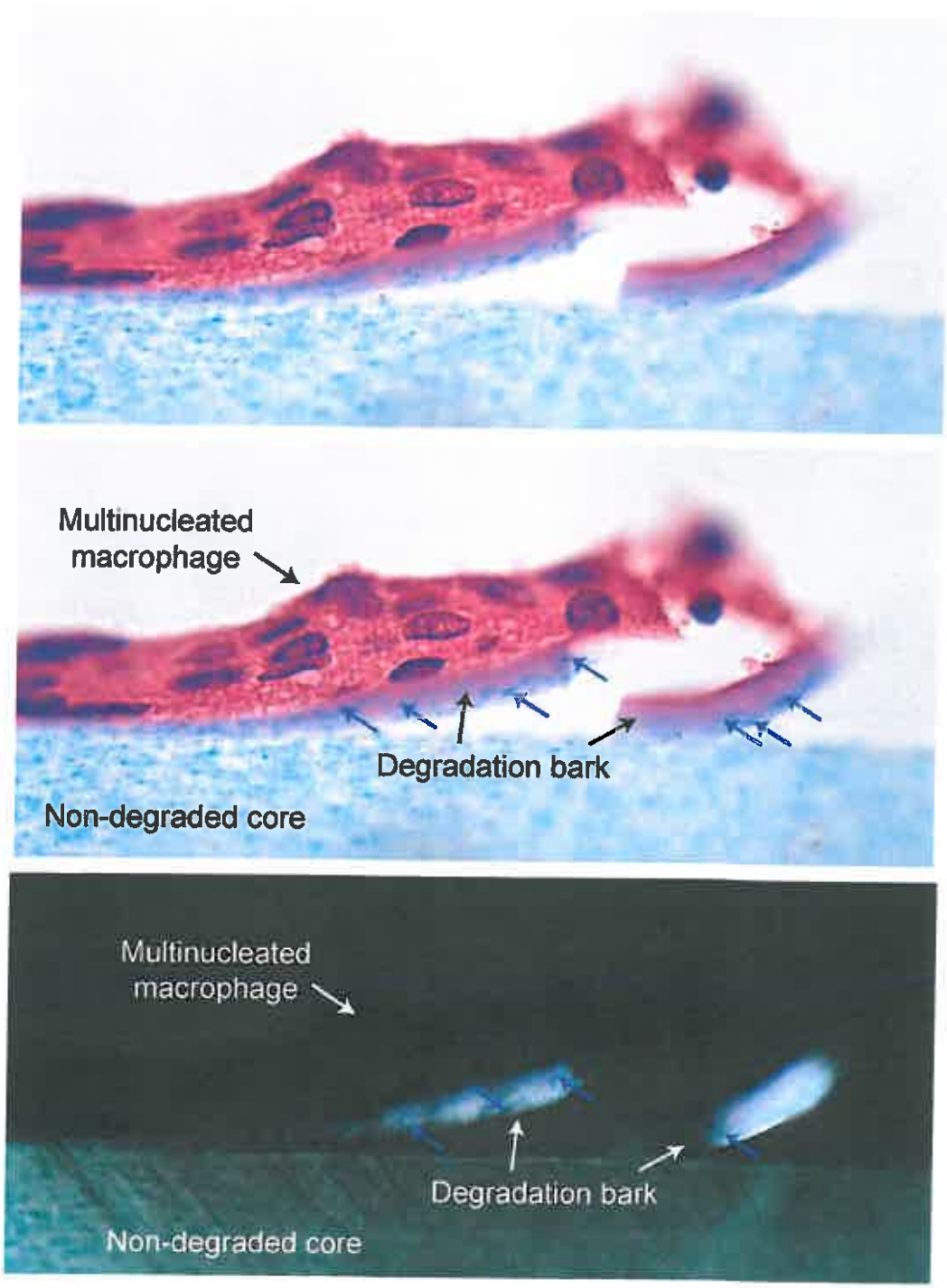


Figure set 13e.Polypropylene degradation layer in regular (upper panels) and the same field in polarized light (lower panel), H&E, 100x.

In this field the bark detached from the core and neither its birefringence nor presence of the blue granules can be explained by an overlap with the core.

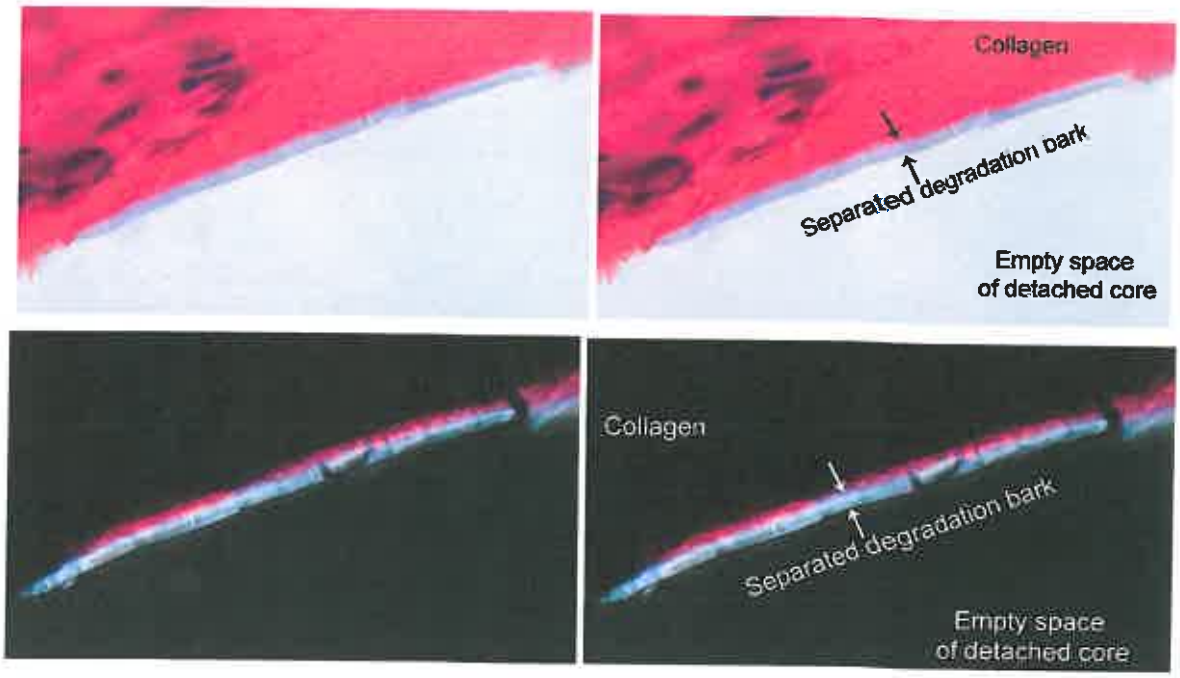


Figure set 13f.Polypropylene degradation layer in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x.

In this field the bark detached from the core and its birefringence cannot be explained by light scatter from the core.

Figure set 13g.Cracked polypropylene degradation layer in regular (left) and the same field in polarized light (right), H&E

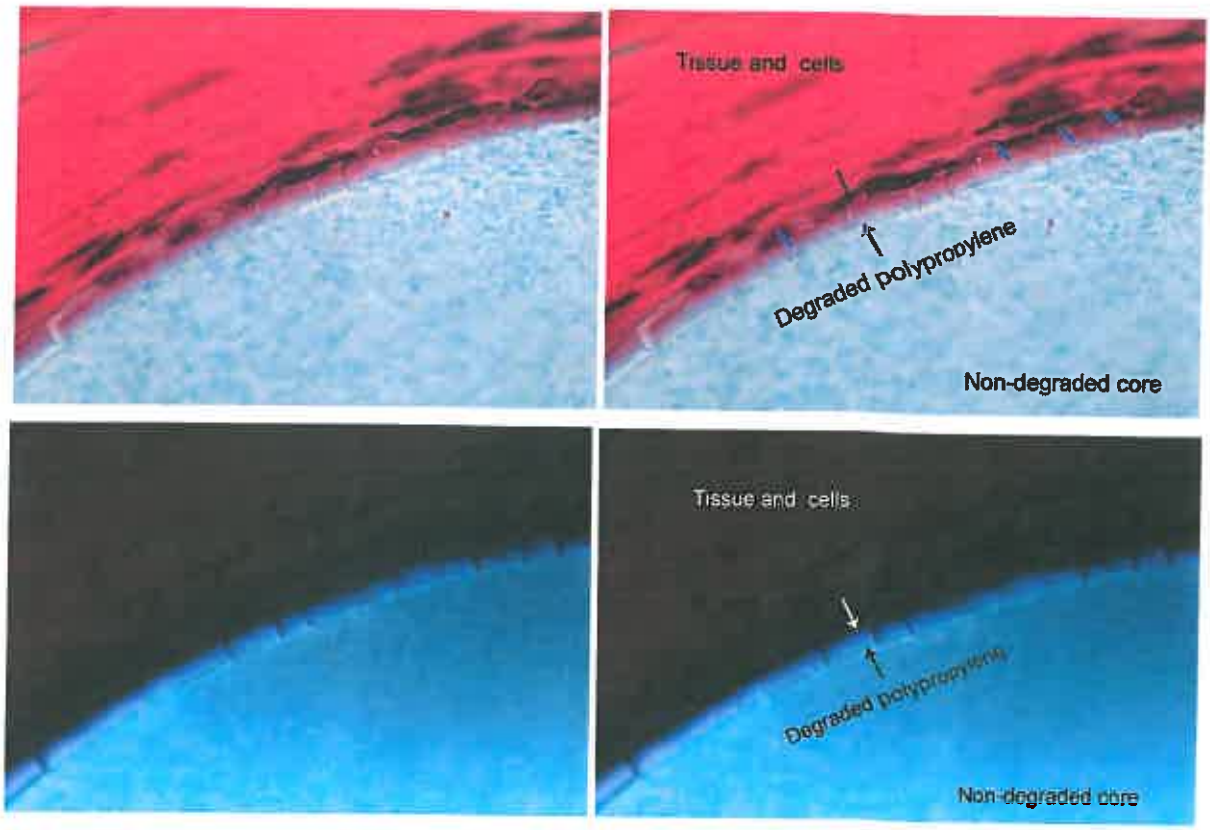


Figure set 13h.Cracked polypropylene degradation layer in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x

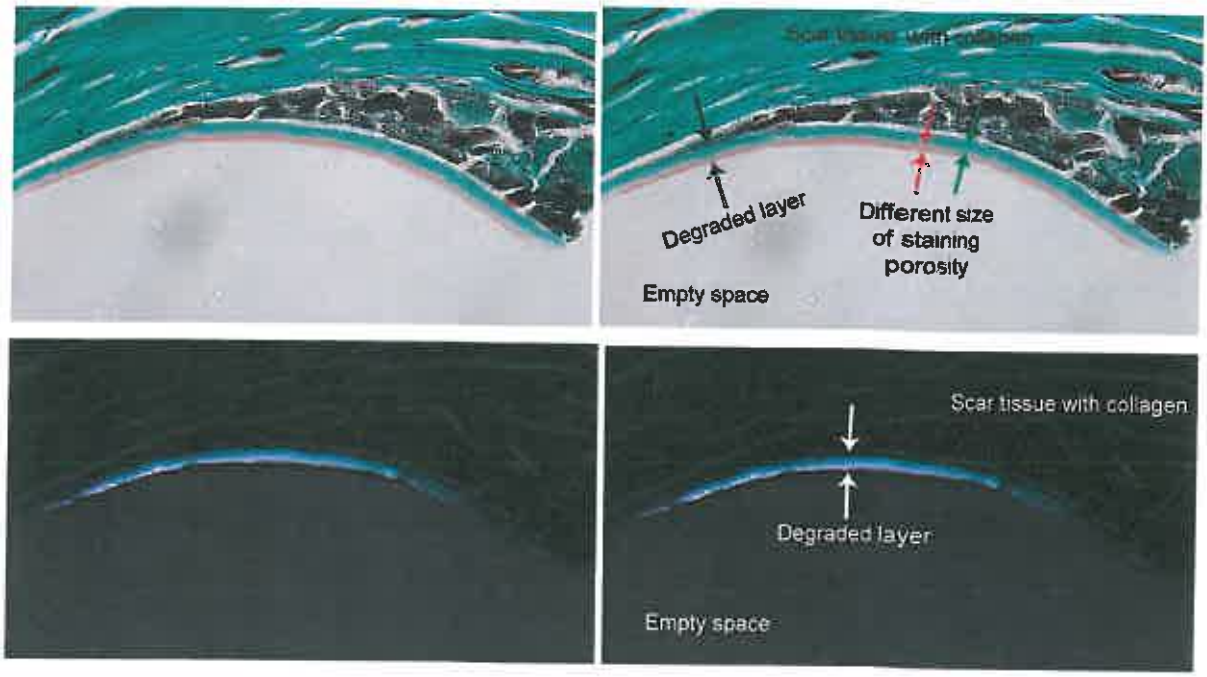


Figure set 13i.Higer degree of degradation and expansion of degradation nanocavities towards the surface of the degradation layer, in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x.

Red dye has smaller molecular size and higher penetration ability. The green dye becomes trapped in the larger nanopores.

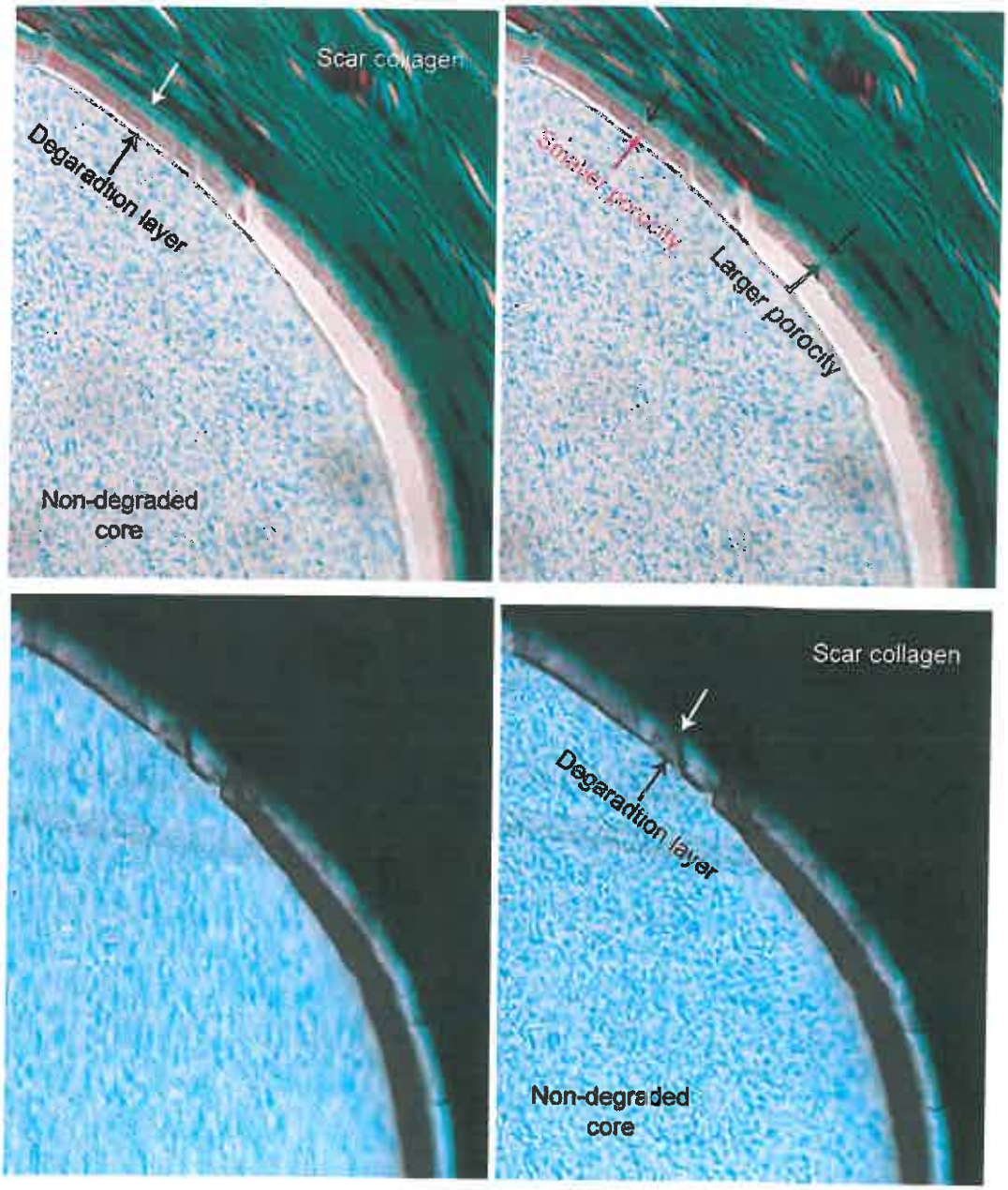


Figure set 13j.Higer degree of degradation and expansion of degradation nanocavities towards the surface of the degradation layer, in regular (upper panel) and the same field in polarized light (lower panel), H&E, 100x.

Red dye has smaller molecular size and higher penetration ability. The green dye becomes trapped in the larger nanopores.

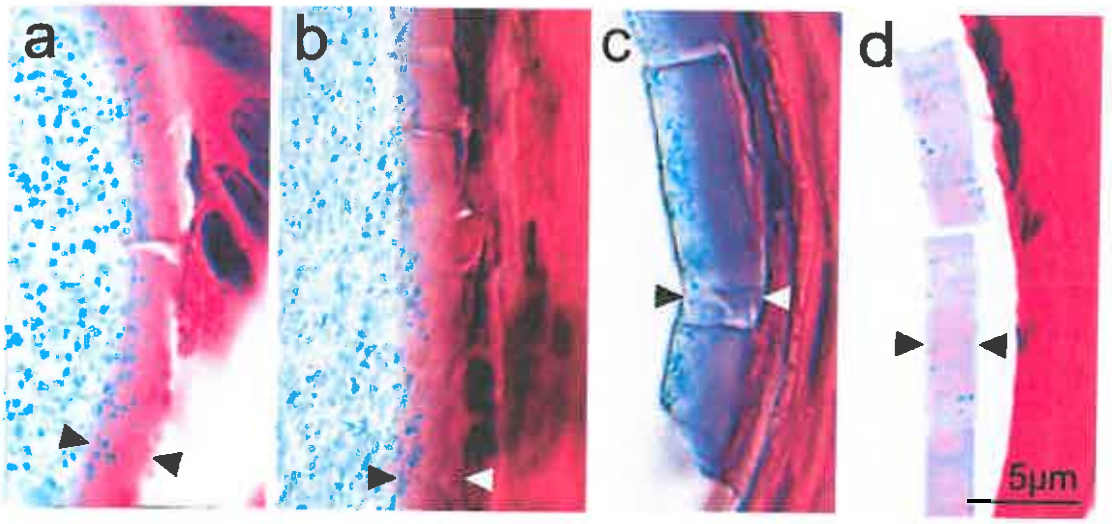


Figure set 13k. Granules of blue dye retained in the degraded layer, images include TVT slings.

[556]

"Degradation "bark" of the blue fibers manufactured with inclusion of blue dye granules, H&E stain, 100x objective with oil immersion: (a) and (b) non-degraded core (left half of the images) and the degraded layer (between arrowheads). Note that the blue granules are retained in the layer of degraded polypropylene. Within the degraded "bark", the granules degrade and loose color toward the surface. In (c) and (d) the non-degraded core detached from the slides similarly to Figure 2(c and d). At these sites, presence of the granules in the separated "bark" cannot be attributed to an overlap with the core."

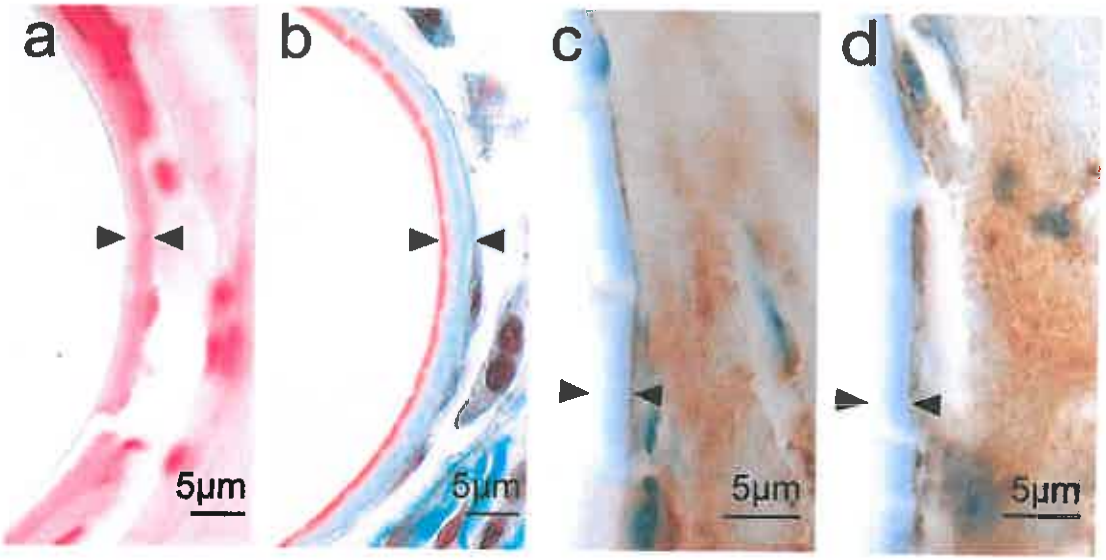


Figure set 13l. Additional stains, images include TVT sling. [556]

"Additional stains, all images taken with 100x oil immersion objective and cropped to a different magnification, polypropylene degradation layer is pointed between arrowheads: (a) Von Kossa stain is negative for calcium in the brittle "bark" (would stain calcium black), (b) trichrome stain shows that the deeper parts of the "bark" have smaller staining porosity (red) than those close to the surface (green) which correlates with TEM findings [Figure 6(b)], (c) immunohistochemical stain for immunoglobulin G (IgG, stained brown). IgG is present in almost all human tissues and fluids. It is deposited on the surface of degraded polypropylene but is not mixed within it. (d) Immunostain for the oxidizing enzyme of inflammatory cells myeloperoxidase (stains brown)."

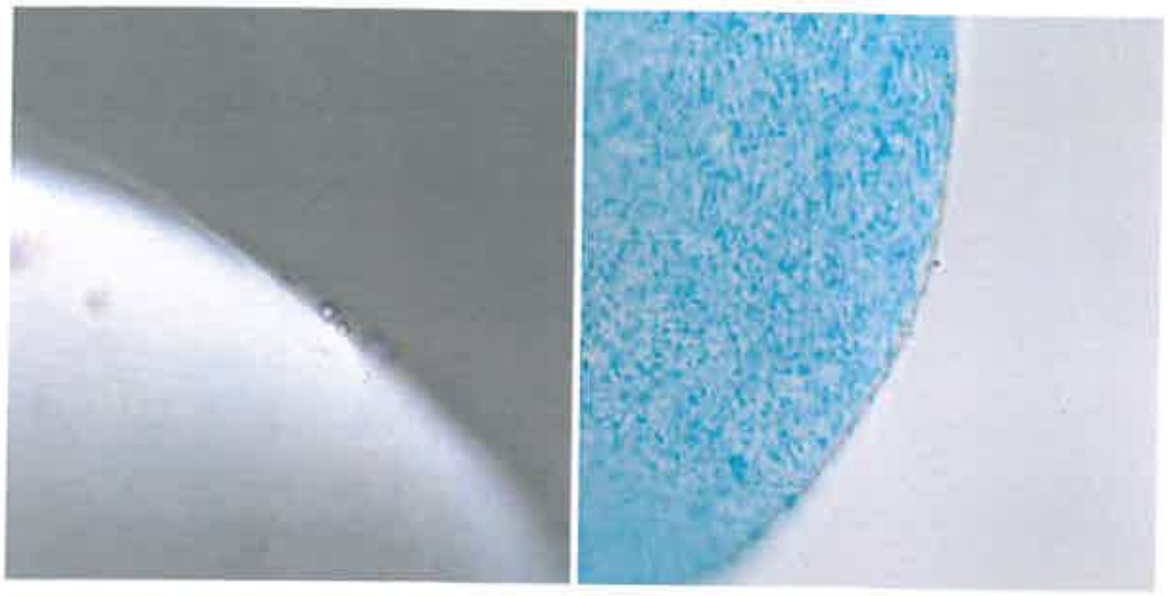


Figure set 14. Absence of degradation in pristine TVT meshes after exposure to formalin (up to 4 months), H&E, 100x.

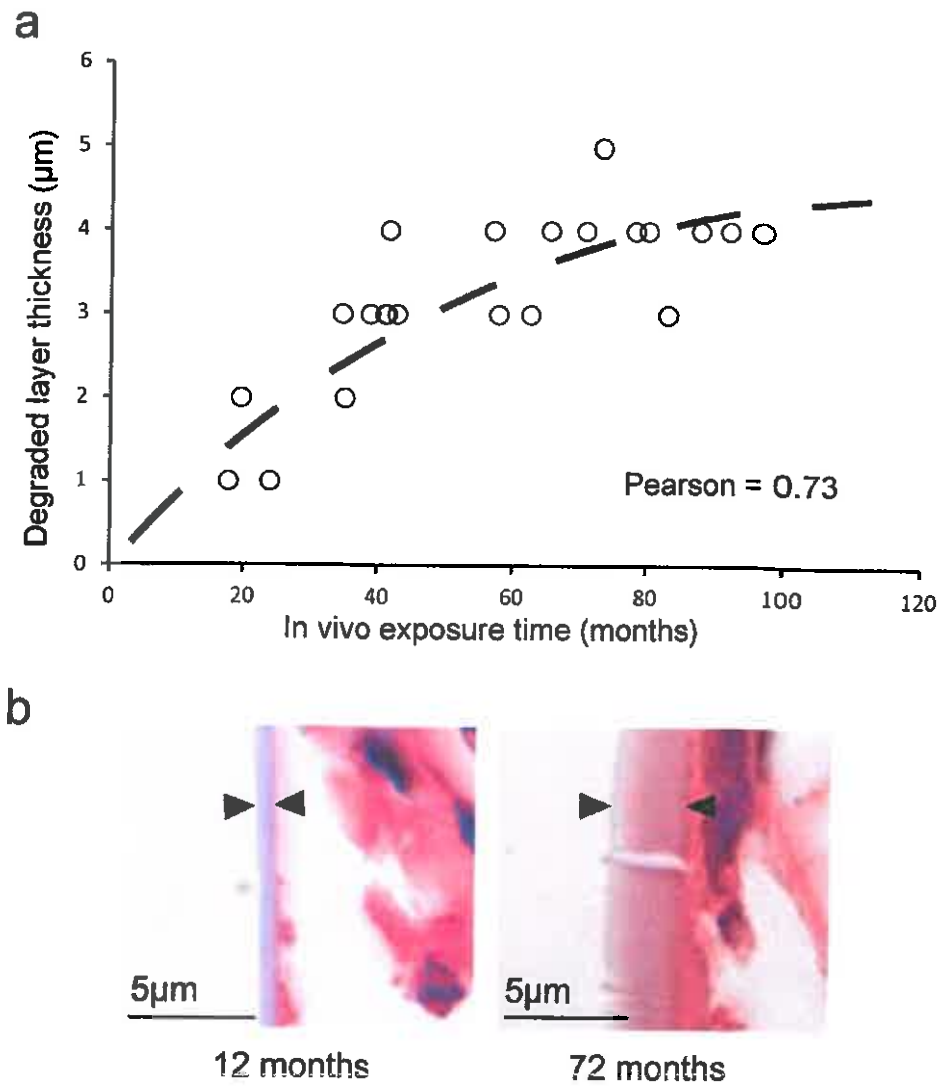


Figure set 15. TVT meshes analyzed as a group. [556]:

"Duration of in vivo exposure versus thickness of degraded layer in a group of explants of the same manufacturer and the same mesh design. (a) Thickness of the degradation "bark" increased over the years in vivo (Pearson correlation50.73). Note the trend of plateauing after 5–6 years. There was no correlation of the thickness with the duration of specimen storage in formalin (not shown, Pearson520.06). (b) Comparison of the "bark" in meshes explanted after 12 and 72 months in the body, H&E, 3100 objective with oil immersion, images cropped to the same magnification factor."

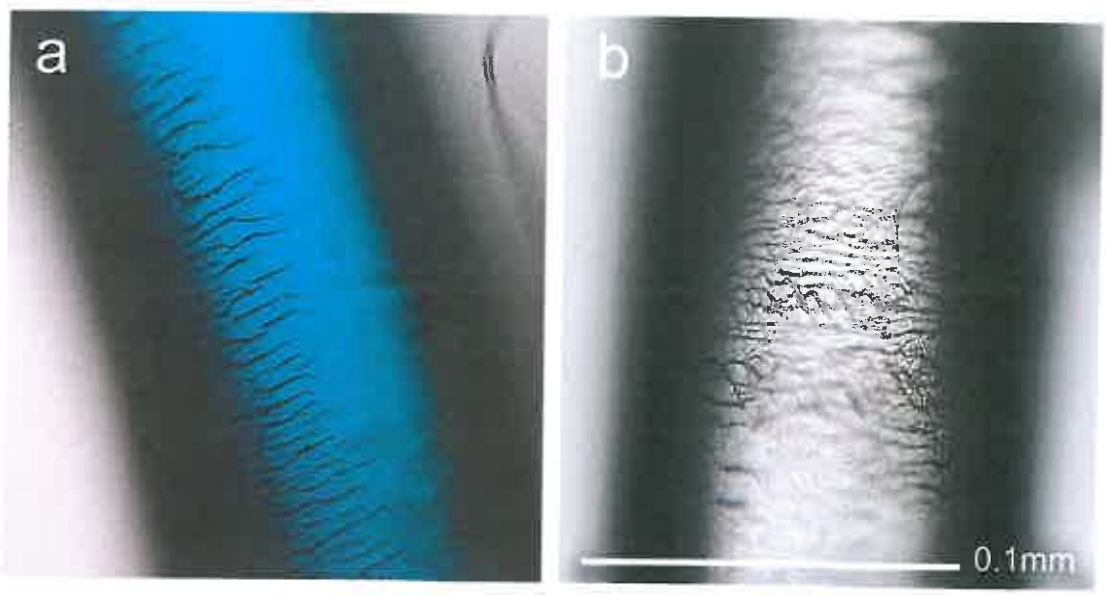


Figure set 16a. Cracking on the surface of TVT mesh fibers immediately after removal from the body. [556]:

"Surface of the mesh fibers immediately after explantation from the body, transvaginal sling explanted due to pain 9 years after implantation, light microscope, 20x objective with image crop. Mesh fibers at the specimen edges had no covering tissue and could be examined as they were in the body, avoiding possible artifacts of tissue removal, drying or contact with formalin. Both blue (a) and clear (b) fibers showed surface cracking."

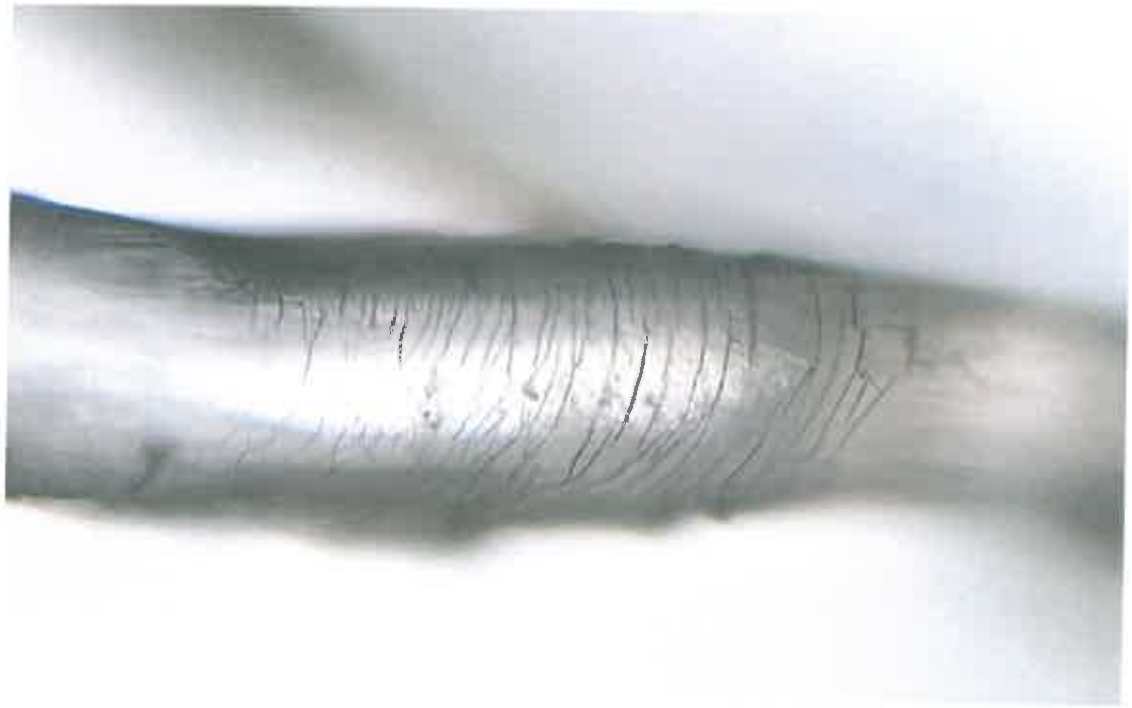


Figure set 16b. Cracking on the surface of TVT mesh fibers.
The microphotograph is composed of images focused at different planes. The mesh fiber was examined in regular light microscope before the specimen was divided (photo below). The examined and photographed mesh fiber was in the portion which was taken by the defense expert (arrow).

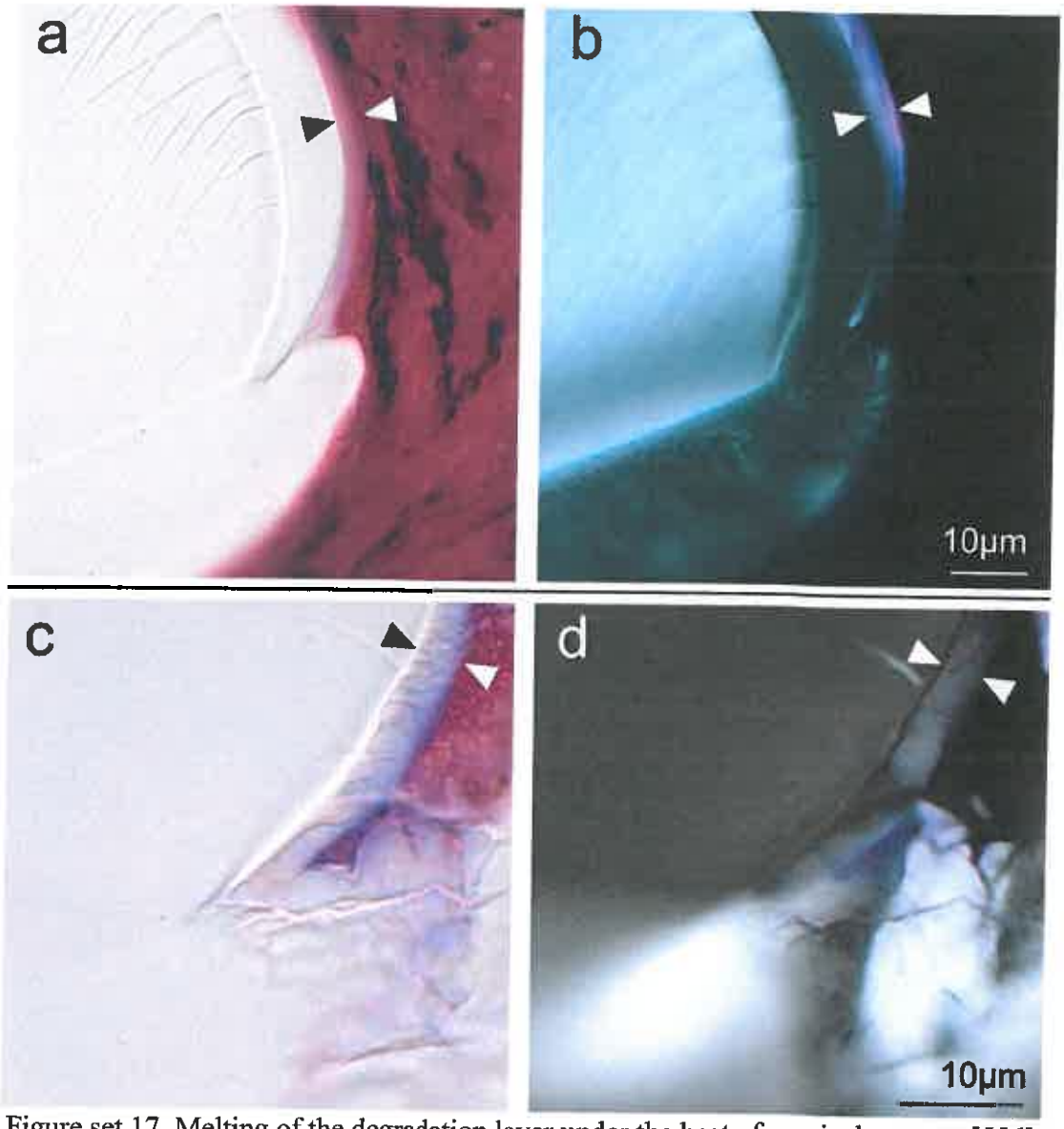


Figure set 17. Melting of the degradation layer under the heat of surgical cautery. [556]

"Melting of both non-degraded and degraded polypropylene caused by the surgical cautery, H&E, 100x oil immersion: (a) and (b) the same site of fiber melting in regular and polarized light, (c) and (d) another site showing melding point. While molten the non-degraded core and the degradation "bark" formed a common pool of material."

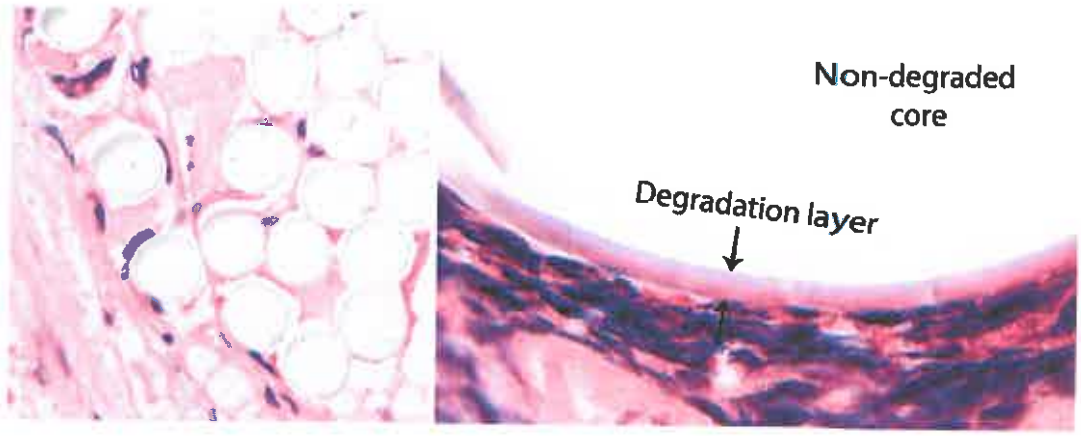


Figure set 18a. Comparison of a non-polypropylene suture on the left and Prolene mesh on the right implanted at the same time, H&E, 100x objective.

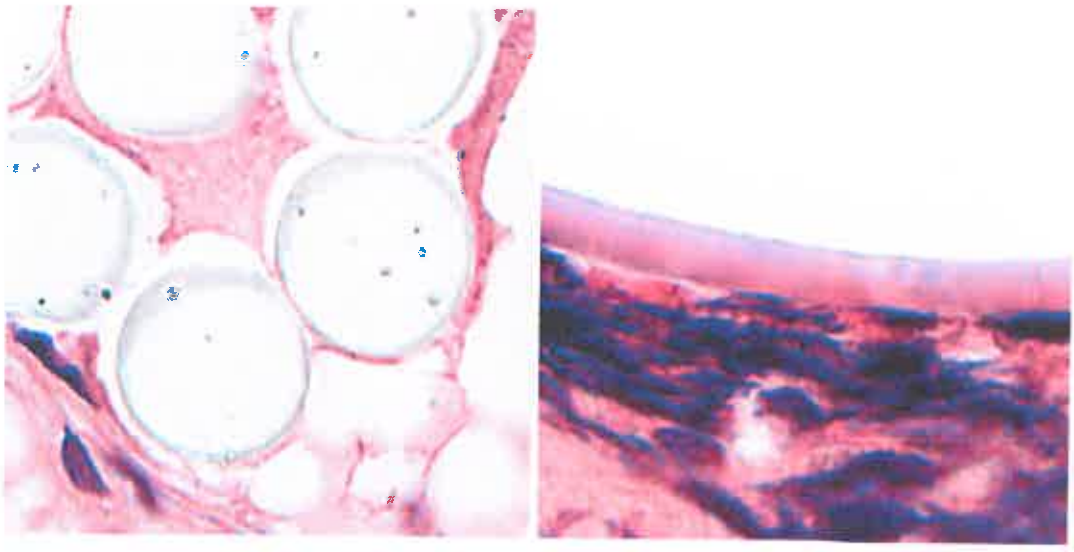


Figure set 18b. Cropped to the same magnification factor, non-polypropylene multifilament suture on the left and Gynemesh (polypropylene) on the right, H&E, 100x objective.
Both materials have been implanted at the same time. The multifilament suture fibers do not have any outer layer. Polypropylene formed a layer of altered material.

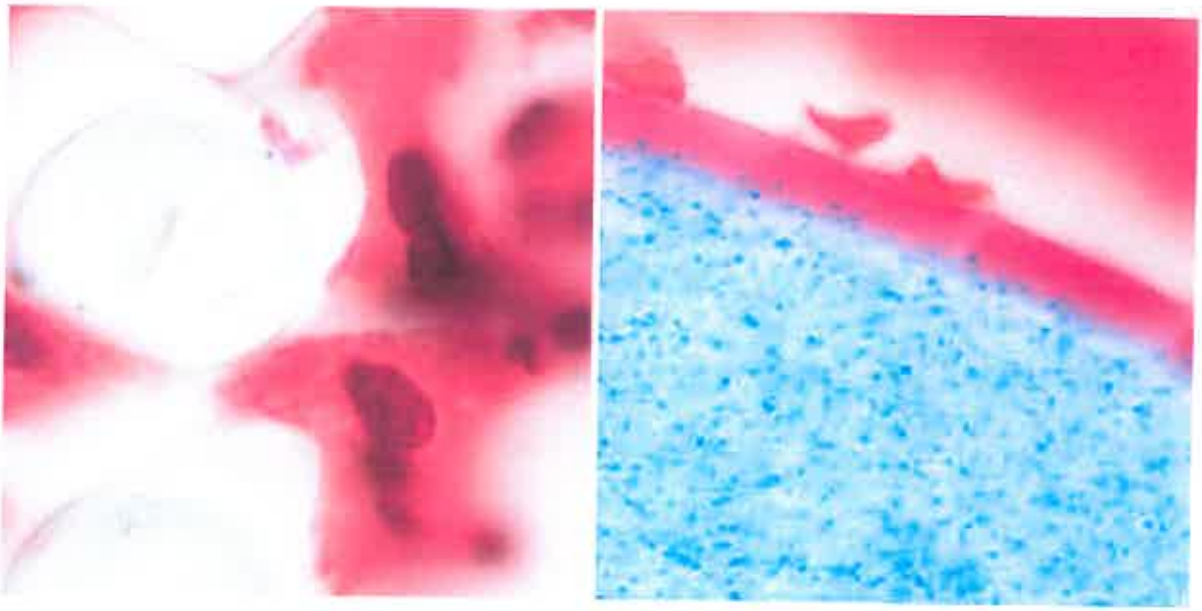


Figure set 18c. Another case of a multifilament suture present in the specimen, cropped to the same magnification factor, non-polypropylene multifilament suture on the left and a TVT fiber (polypropylene) on the right, H&E, 100x objective.

Both materials have been implanted at the same time. The multifilament suture fibers do not have any outer layer. Polypropylene formed a layer of altered material.

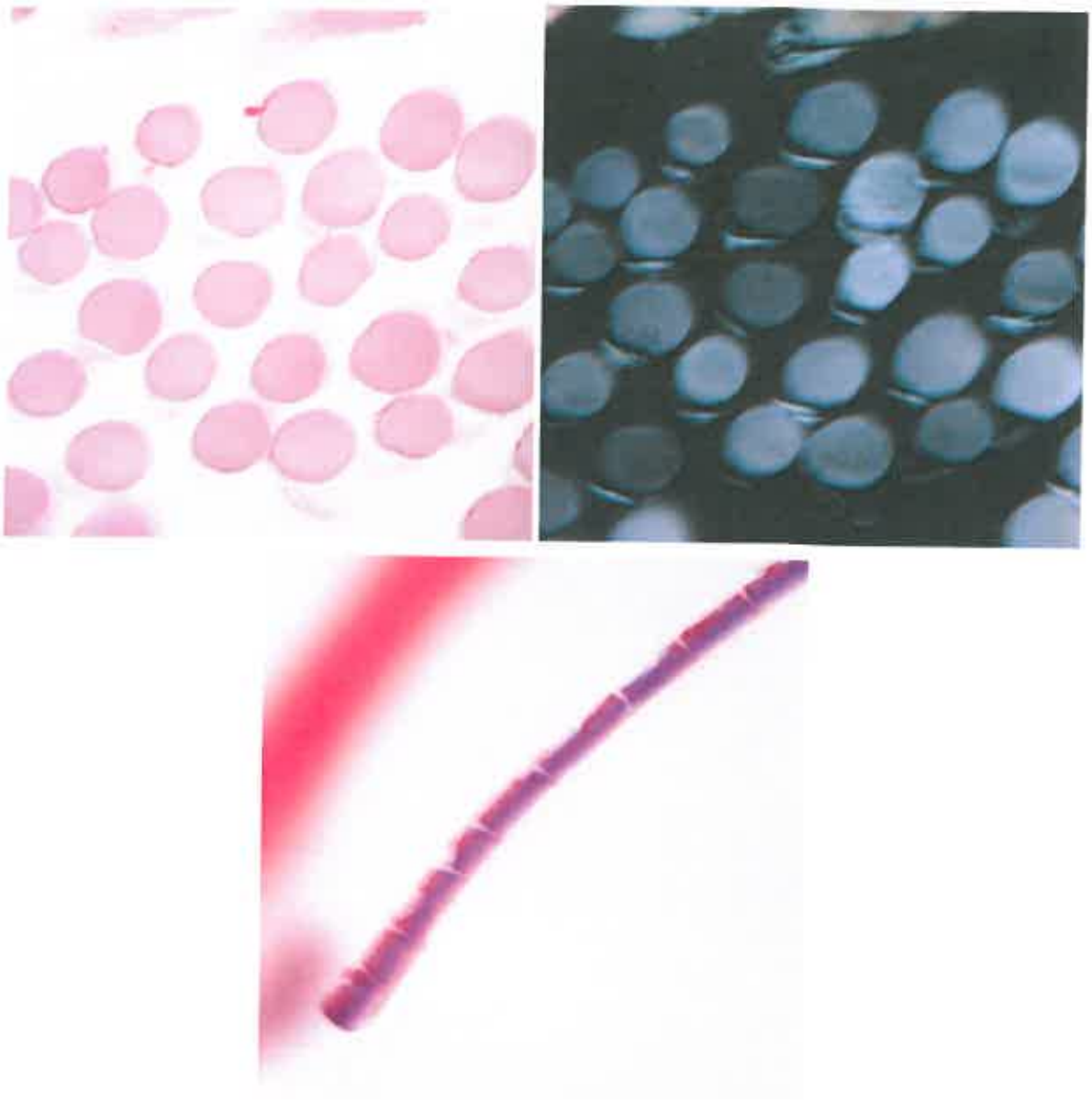


Figure set 18d. Cropped to the same magnification factor, non-polypropylene multifilament suture at the top and a TVT (polypropylene) in the lower image, H&E, 100x objective.
In this case the suture was used intraoperatively and had no in vivo exposure to the body. Note that the matrial absorbed the dye. Although non-degraded, a porous polymer can absorb dyes. The finding shows a non-specific non-chemical (not covalent) nature of staining.

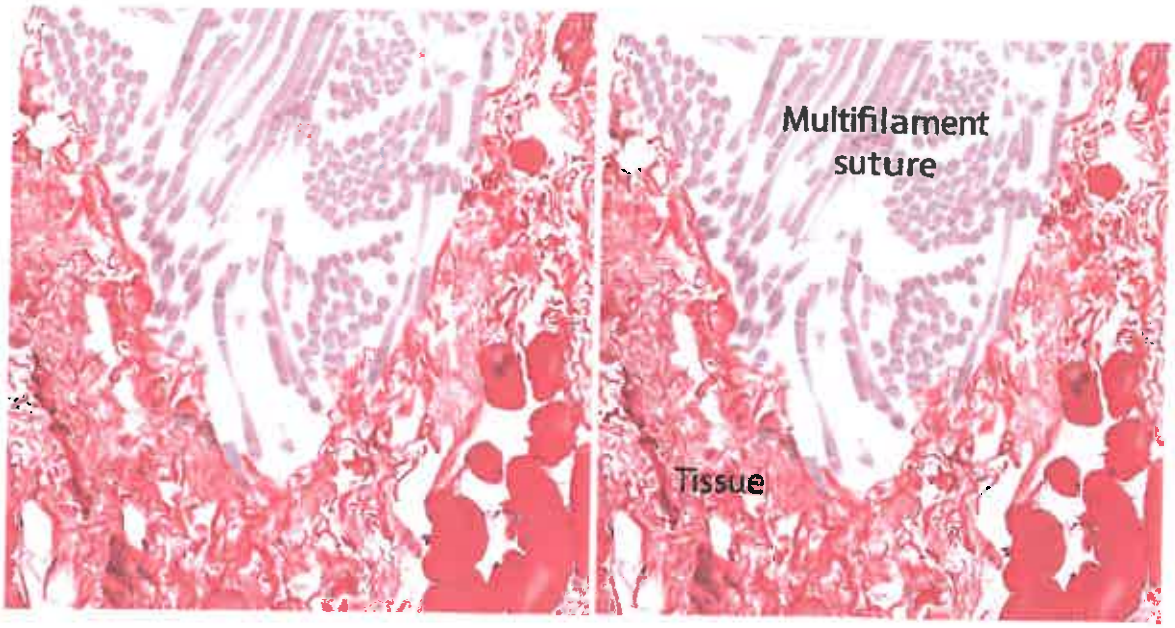
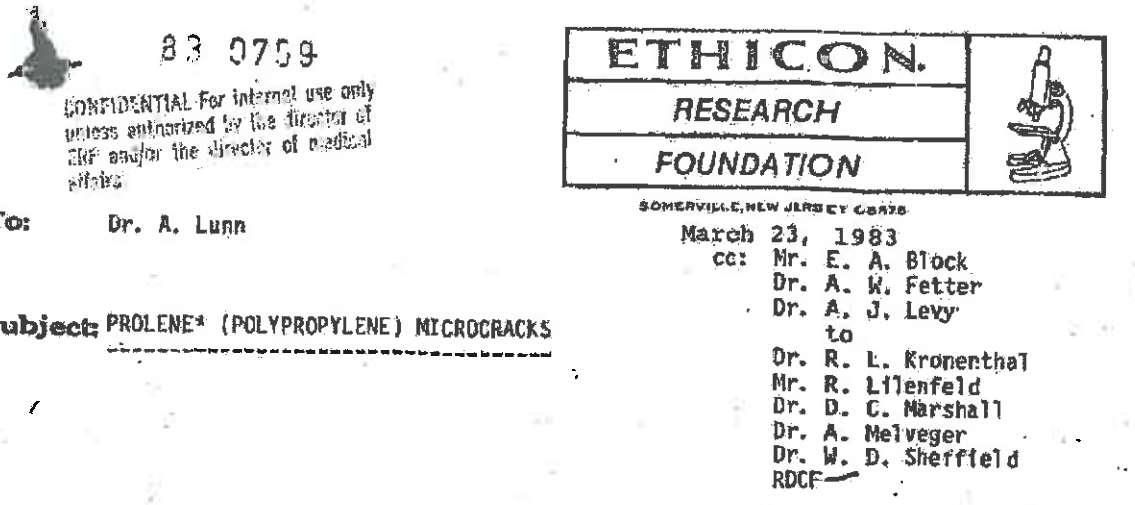


Figure set 18e. Image shows that there is no vital reaction to the multifilament suture, H&E, 20x objective.

The suture had no exposure to the body, it was used during the exscision surgery.

Images and text from the Ethicon study using identical methodology to detect degradation of polypropylene.



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FOUNDATION
SOMERVILLE, NEW JERSEY 08876

To: Dr. A. Lunn

March 23, 1983

cc: Mr. E. A. Block
Dr. A. W. Fetter
Dr. A. J. Levy
to
Dr. R. L. Kronenthal
Mr. R. Lilenfeld
Dr. D. C. Marshall
Dr. A. Melveger
Dr. W. D. Sheffield
RDCF

Subject: PROLENE* (POLYPROPYLENE) MICROCRACKS

Figure set 19a.

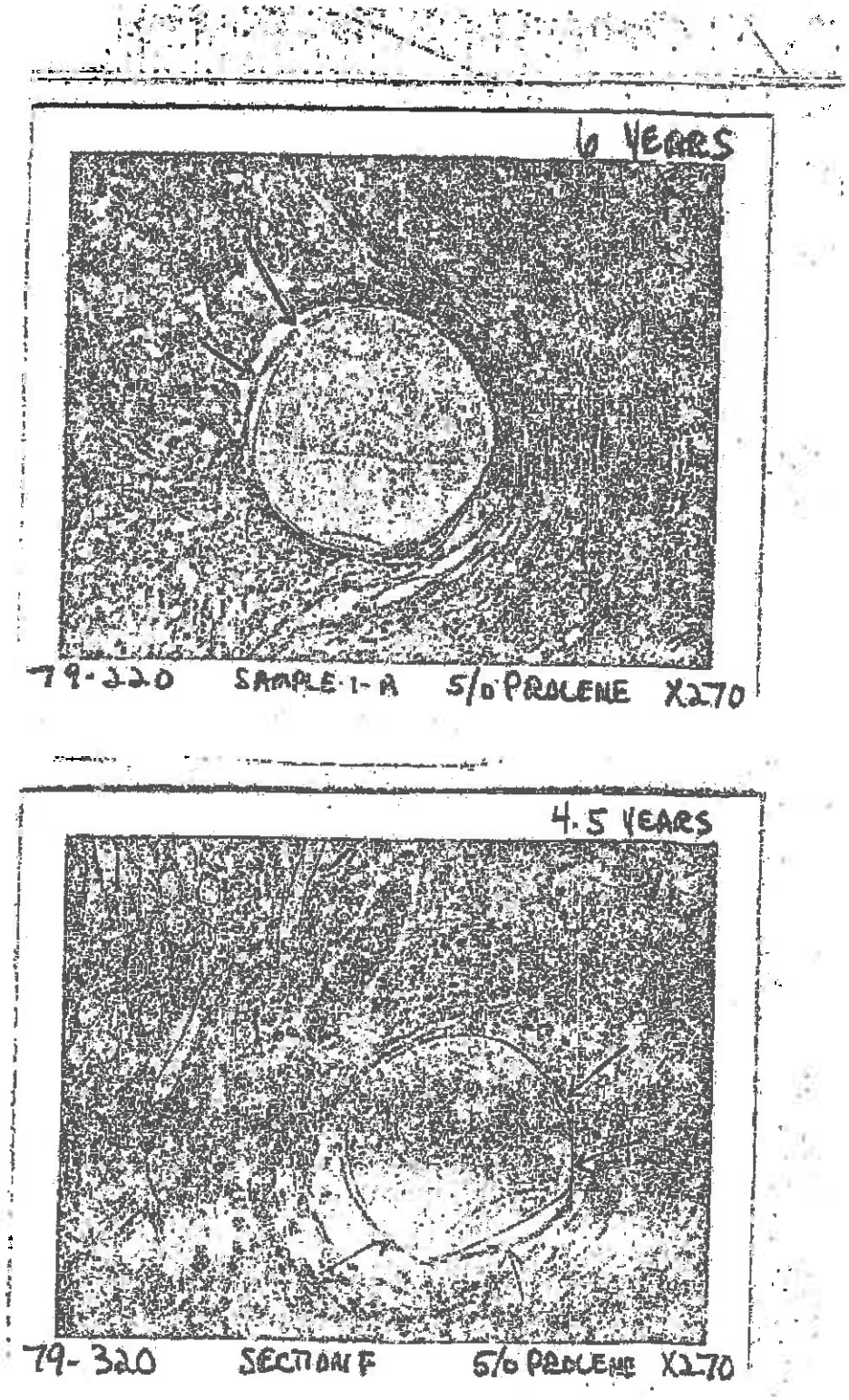

Figure set 19b.

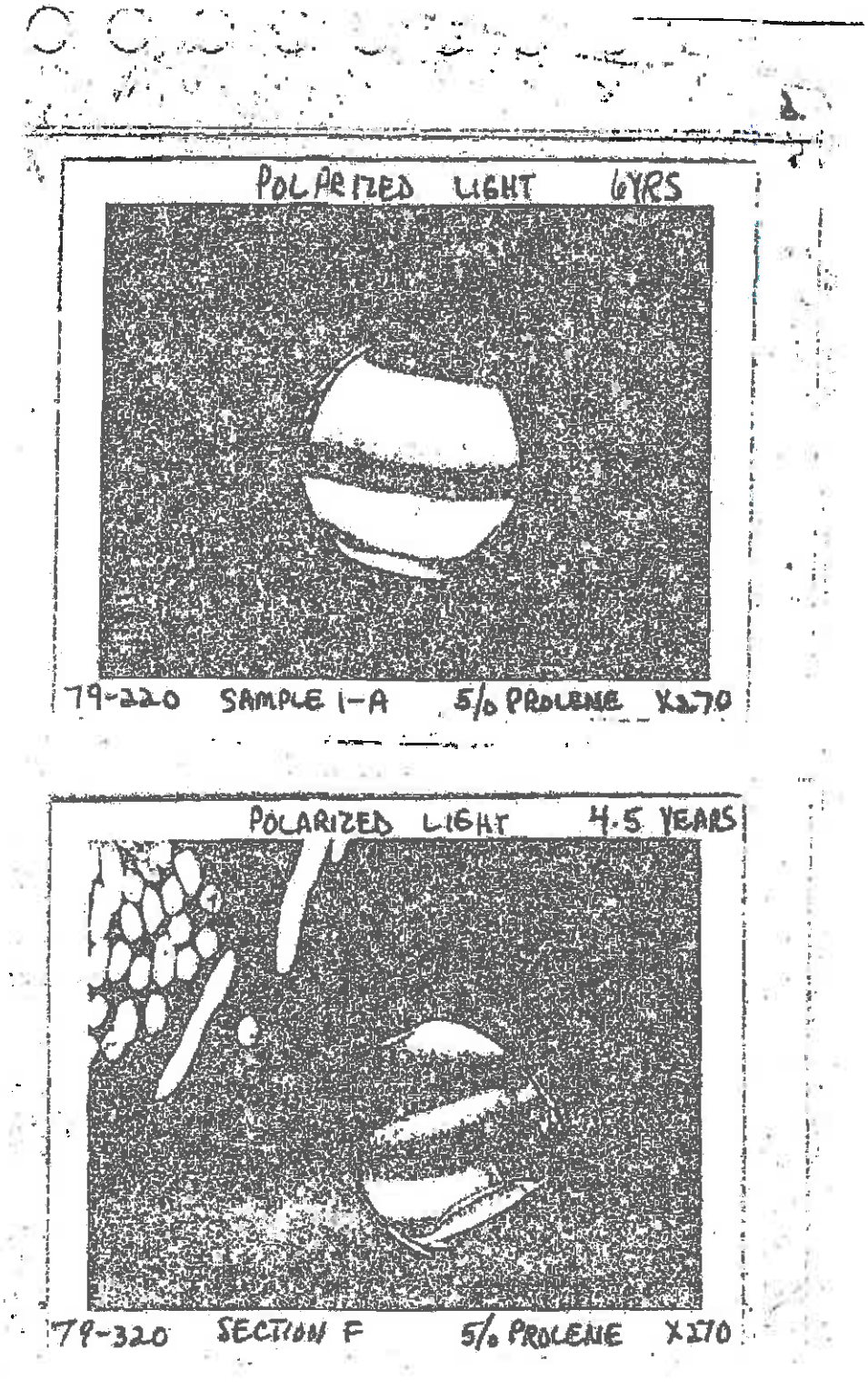

Figure set 19c.

In histological sections of sample 6, a cracked surface layer measuring 3.0-4.5 microns was seen, accounting for approximately 8.5% of the total cross-sectional area. This layer was birefringent when examined under polarized light microscopy. Phloxine stain had completely penetrated the cracked layer, Figure 5, or was confined to the periphery of the surface layer, Figure 6. Particles of blue dye were evident within the cracked layer, Figure 5. There was no evidence of migration of particles from the cracked surface layer into the surrounding tissue.

DISCUSSION

In this study, it was shown that a 5-0 PROLENE suture in residence within a human vascular graft for 7 years displayed surface cracking. Other specimens of size 3-0 and 4-0 in this study from cardiovasular tissue specimens did not show surface cracking. The depth of the cracking in sample #6 was 3.0 - 4.5 microns in thickness which is consistent with other specimens, from previous samples up to 6 years post-op, ERF 84-132. This additional evidence from a 7 year specimen suggests no increase in thickness

of the cracked layer over time. The cracked layer appeared blue in gross specimens and blue dye particles were evident in histological sections of the layer. This would indicate that the layer is dyed PROLENE polymer and not an isolated protein coating on the strands.

Figure set 19d.

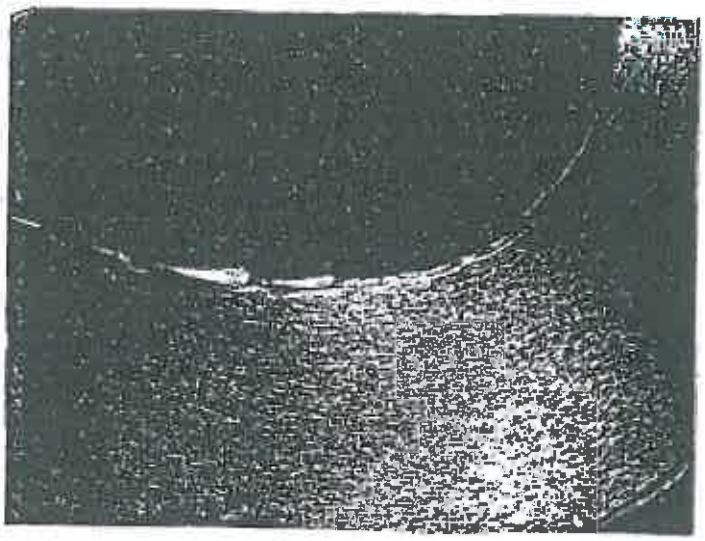

Figure 5 - Histological longitudinal sections of PROLENE from sample 6, block A, Phloxine stained. A 3.0-4.5 micron cracked surface layer is birefringent when viewed with polarized light, magnification x300.

Figure set 19e. Image from the 1983 Ethicon study.

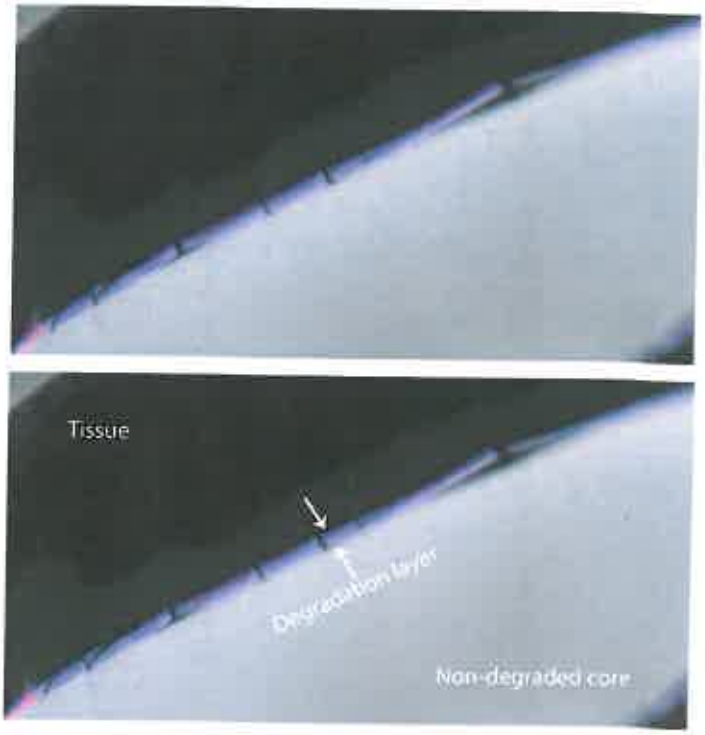

Figure set 19f. Image taken in 2015.

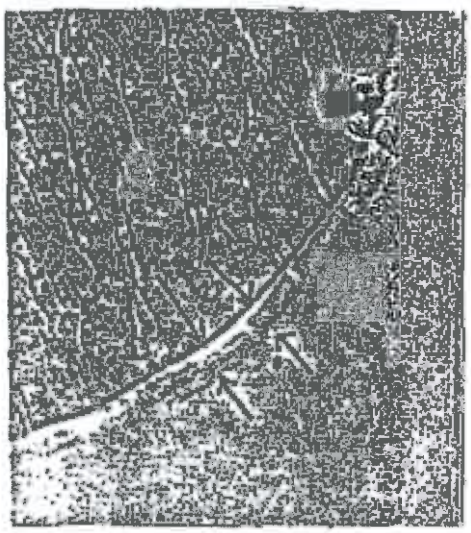

Figure 6 - Histological cross-section of sample 6, block D, Phloxine stained. Pink staining is limited to the periphery of the cracked layer in some areas. Blue dye particles can be seen within the cracked layer, magnification x1100.

Figure set 19g. Image from the 1983 Ethicon study.

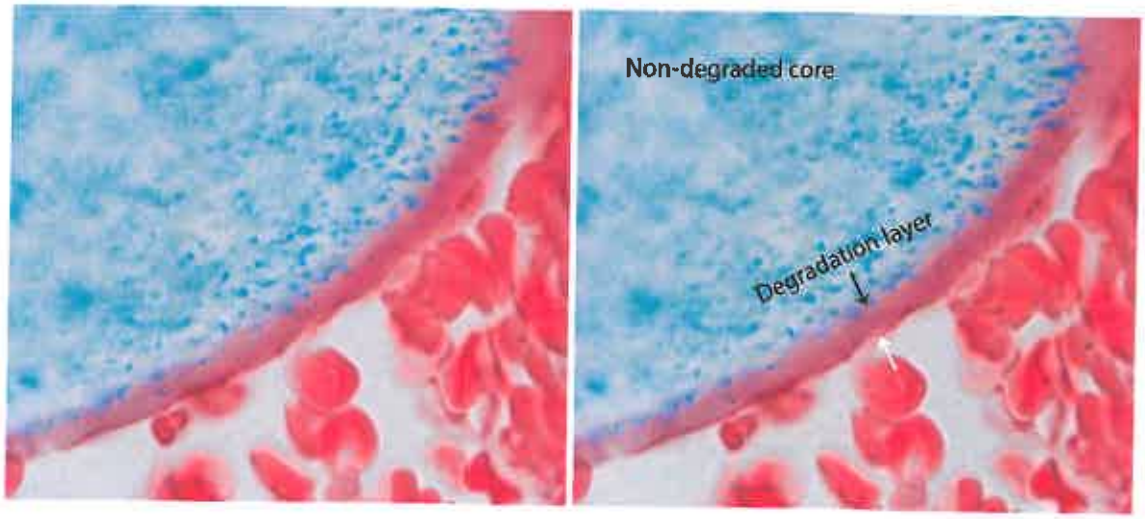

Figure set 19h. Image taken in 2015. Blue dye particles = blue granules; have also been as an internal marker of polypropylene in the 1983 Ethicon study.

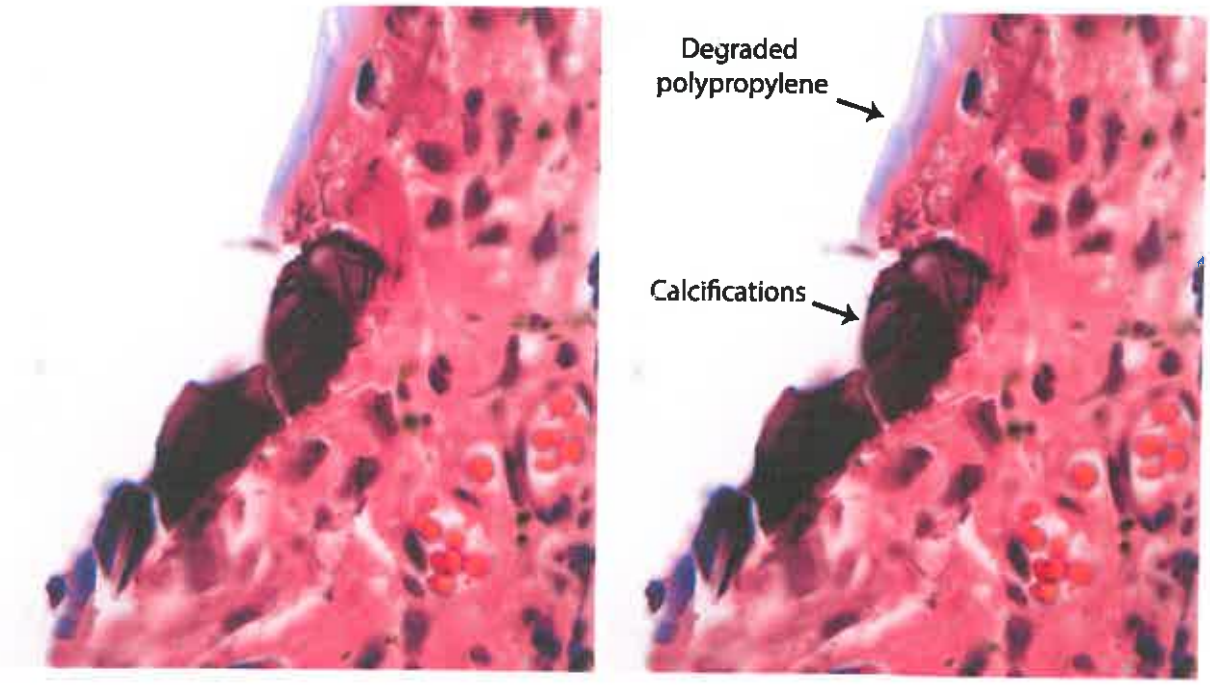

Figure set 20a. Degenerative calcifications triggered by the mesh and the body reaction to it, H&E, x100.

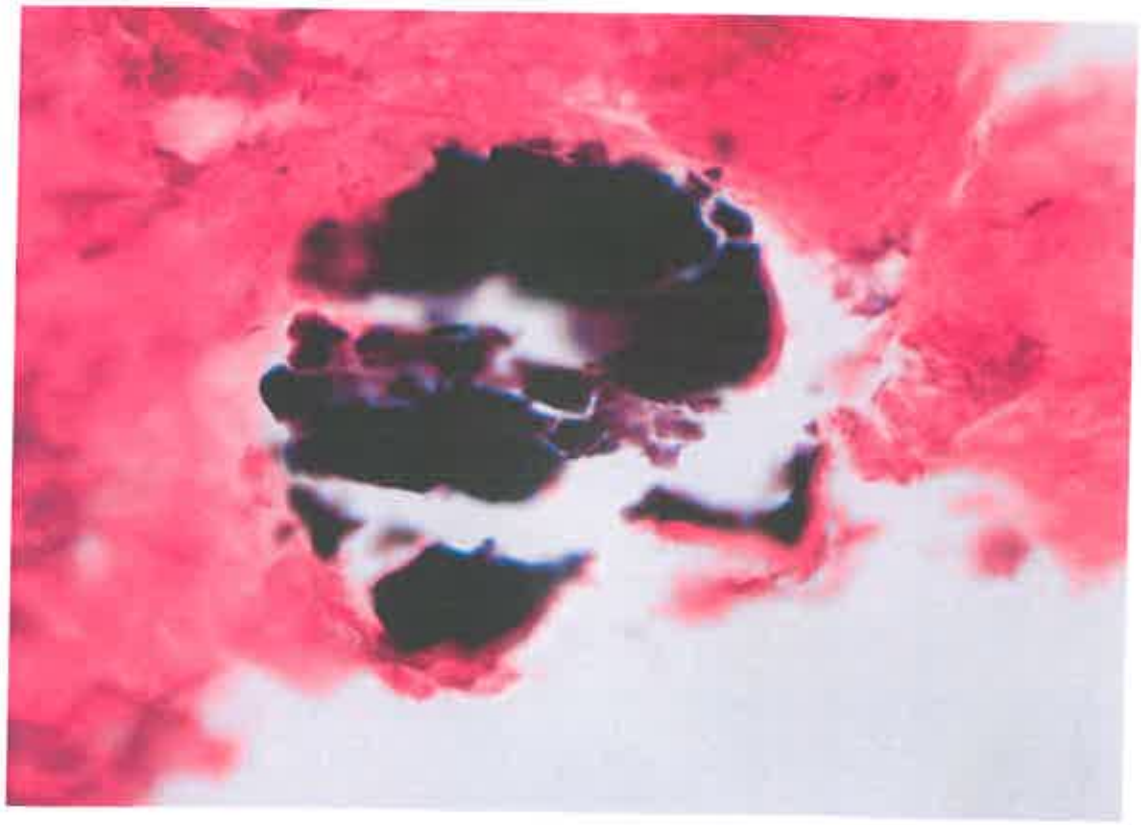

Figure set 20b. Degenerative calcifications triggered by the mesh and the body reaction to it, H&E, x100.In cases wre the mesh migrates into the bladder these calcifications can grow to large bladder stones [589-594].

Reliance materials

1. Abbot, S., Evani, J. M., et al. (2013). Evaluation and management of complications from synthetic mesh after pelvic reconstructive surgery: A multi-center study. AUGS Paper 29.
2. Abdel-fattah, M., Mostafa, A., Young, D. & Ramsay, I. Evaluation of transobturator tension-free vaginal tapes in the management of women with mixed urinary incontinence: one-year outcomes. Am J Obstet Gynecol 205, 150 e1-6 (2011).
3. Abdel-Fattah, M., Sivanesan, K., Ramsay, I., Pringle, S., & Bjornsson, S. (2006). How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. BJU Int, 98(3), 594-598.
4. Abdelwahab, O., Shedid, I., & Al-Adl, A. M. (2010). Tension-Free Vaginal Tape versus Secure Tension-Free Vaginal Tape in Treatment of Female Stress Urinary Incontinence. Current Urology, 4(2), 93-98.
5. Abed, H., Rahn, D. D., Lowenstein, L., Balk, E. M., Clemons, J. L., & Rogers, R. G. (2011). Incidence and management of graft erosion, wound granulation, and dyspareunia following vaginal prolapse repair with graft materials: a systematic review. Int Urogynecol J, 22(7), 789-798. doi: 10.1007/s00192-011-1384-5
6. Abouassaly, R. et al. Complications of tension-free vaginal tape surgery: a multi-institutional review. BJU Int 94, 110-113 (2004).
7. ACOG Practice Bulletin Pelvic Organ Prolapse Number 85, September 2007
8. Agostini, A. et al. Abscess of the thigh and psoas muscle after transobturator suburethral sling procedure. Acta Obstet Gynecol Scand 85, 628-9 (2006).
9. Agostini, A. et al. Immediate complications of tension-free vaginal tape (TVT): results of a French survey. Eur J Obstet Gynecol Reprod Biol 124, 237-9 (2006).
10. Agrawal, A. & Avill, R. Mesh migration following repair of inguinal hernia: a case report and review of literature. Hernia 10, 79-82 (2006).
11. Aigmueller, T. et al. Ten-year follow-up after the tension-free vaginal tape procedure. Am J Obstet Gynecol 205, 496 e1-5 (2011).
12. Ala-Nissila, S., Haarala, M. & Makinen, J. Tension-free vaginal tape - a suitable procedure for patients with recurrent stress urinary incontinence. Acta Obstet Gynecol Scand 89, 210-6 (2010).
13. Al-Badr, A. & Fouda, K. Suprapubic-assisted cystoscopic excision of intravesical tension-free vaginal tape. J Minim Invasive Gynecol 12, 370-1 (2005).
14. Albino, F. et al. Does mesh location matter in abdominal wall reconstruction? A systematic review of the literature and a summary of recommendations. Plast Reconstr Surg 132, 1295-304 (2013).
15. Albo, M. et al. Treatment Success of Retropubic and Transobturator Mid Urethral Slings at 24 Months. J Urol 188, 2281-7 (2012).
16. Albrecht, K. in Technology and Society (ISTAS), 2010 IEEE International Symposium on 337-349 (2010).
17. Ali SAM, Doherty P J, Williams DF. The Mechanisms of Oxidative Degradation of Biomedical Polymers by Free Radicals. J Appl Poly Sci 1994; 51:1389-1398.
18. Al-Singary, W. et al. Trans-obturator tape for incontinence: a 3-year follow-up. Urol Int 78, 198-201 (2007).
19. Altman, D., Anzen, B., Morlin, B. & Falconer, C. Tension-free vaginal tape after failed cystoscopic transurethral injections for stress urinary incontinence. Scand J Urol Nephrol 43, 506-8 (2009).
20. Altman, D., Vayrynen, T., Engh, M. E., Axelsen, S., & Falconer, C. (2011). Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med, 364(19), 1826-1836. doi: 10.1056/NEJMoa1009521

21. Al-Wadi, K. & Al-Badr, A. Martius graft for the management of tension-free vaginal tape vaginal erosion. Obstet Gynecol 114, 489-91 (2009).
22. Amid, P.K., Shulman, A.G., Lichtenstein, I.L. & Hakakha, M. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir 379, 168-71 (1994).
23. Ammendrup, A.C., Jorgensen, A., Sander, P., Ottesen, B. & Lose, G. A Danish national survey of women operated with mid-urethral slings in 2001. Acta Obstet Gynecol Scand 88, 1227-33 (2009).
24. Anderson, J. & Miller, K. Biomaterial biocompatibility and the macrophage. Biomaterials 5, 5-10 (1984).
25. Anderson, J. Biological Responses to Materials. Annual Review of Materials Research 31, 81-110 (2001).
26. Andonian, S., St-Denis, B., Lemieux, M.C. & Corcos, J. Prospective clinical trial comparing Obtape and DUPS to TVT: one-year safety and efficacy results. Eur Urol 52, 245-51 (2007).
27. Andrada Hamer, M., Larsson, P.G., Teleman, P., Bergqvist, C.E. & Persson, J. One-year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogynecol J 24, 223-9 (2013).
28. Anger, J.T. et al. Short-term outcomes of vaginal mesh placement among female Medicare beneficiaries. Urology 83, 768-73 (2014).
29. Anger, J.T., Rodriguez, L.V., Wang, Q., Pashos, C.L. & Litwin, M.S. The role of preoperative testing on outcomes after sling surgery for stress urinary incontinence. J Urol 178, 1364-8; discussion 1368-9 (2007).
30. Angioli, R. et al. Suburethral sling in autoimmune patients: complications, quality of life, and success rate. Int Urogynecol J 23, 453-7 (2012).
31. Angioli, R. et al. Tension-free vaginal tape versus transobturator suburethral tape: five-year follow-up results of a prospective, randomised trial. Eur Urol 58, 671-7 (2010).
32. Aniuliene, R. Tension-free vaginal tape versus tension-free vaginal tape obturator (inside-outside) in the surgical treatment of female stress urinary incontinence. Medicina (Kaunas) 45, 639-43 (2009).
33. Ankardal, M., Heiwall, B., Lausten-Thomsen, N., Carnelid, J. & Milsom, I. Short- and long-term results of the tension-free vaginal tape procedure in the treatment of female urinary incontinence. Acta Obstet Gynecol Scand 85, 986-92 (2006).
34. Aponte, M.M. et al. Urodynamics for clinically suspected obstruction after anti-incontinence surgery in women. J Urol 190, 598-602 (2013).
35. Appell, R.A. Primary slings for everyone with genuine stress incontinence? The argument for. Int Urogynecol J Pelvic Floor Dysfunct 9, 249-51 (1998).
36. Araco, F. et al. Results 1 year after the Reemex system was applied for the treatment of stress urinary incontinence caused by intrinsic sphincter deficiency. Int Urogynecol J Pelvic Floor Dysfunct 19, 783-6 (2008).
37. Ark, C., Gungorduk, K. & Celebi, I. Results of TOT operations alone and combined with other vaginal surgical procedures. Aust N Z J Obstet Gynaecol 50, 550-5 (2010).
38. Arrabal-Polo, M. et al. Complications from the Placement of a Tension-Free Suburethral Sling Using the Transobturator and Retropubic Methods for Treatment of Female Urinary Incontinence. Urol Int 89, 97-102 (2012).
39. Ashok, K. & Petri, E. Failures and complications in pelvic floor surgery. World J Urol 30, 487-94 (2012).
40. Atassi, Z., Reich, A., Rudge, A., Kreienberg, R., & Flock, F. (2008). Haemorrhage and nerve damage as complications of TVT-O procedure: case report and literature review. Arch Gynecol Obstet, 277(2), 161-164. doi: 10.1007/s00404-007-0424-3
41. Athanasiou, S. et al. Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? Int Urogynecol J 25, 219-25 (2014).

42. Babalola, E.O., Famuyide, A.O., McGuire, L.J., Gebhart, J.B. & Klingele, C.J. Vaginal erosion, sinus formation, and ischiorectal abscess following transobturator tape: ObTape implantation. Int Urogynecol J Pelvic Floor Dysfunct 17, 418-21 (2006).
43. Ballert, K.N., Kanofsky, J.A. & Nitti, V.W. Effect of tension-free vaginal tape and TVT-obturator on lower urinary tract symptoms other than stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 19, 335-40 (2008).
44. Ballester, M. et al. Four-year functional results of the suburethral sling procedure for stress urinary incontinence: a French prospective randomized multicentre study comparing the retropubic and transobturator routes. World J Urol 30, 117-22 (2012).
45. Bandarian, M., Ghanbari, Z. & Asgari, A. Comparison of transobturator tape (TOT) vs Burch method in treatment of stress urinary incontinence. J Obstet Gynaecol 31, 518-20 (2011).
46. Baracat, F., Mitre, A.I., Kanashiro, H. & Montellato, N.I. Endoscopic treatment of vesical and urethral perforations after tension-free vaginal tape (TVT) procedure for female stress urinary incontinence. Clinics (Sao Paulo) 60, 397-400 (2005).
47. Barber, M. D., Brubaker, L., Nygaard, I., Wheeler, T. L., 2nd, Schaffer, J., Chen, Z., & Spino, C. (2009). Defining success after surgery for pelvic organ prolapse. Obstet Gynecol, 114(3), 600-609. doi: 10.1097/AOG.0b013e3181b2b1ae
48. Barber, M.D. et al. Risk factors associated with failure 1 year after retropubic or transobturator midurethral slings. Am J Obstet Gynecol 199, 666 e1-7 (2008).
49. Barber, M.D. et al. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 119, 328-37 (2012).
50. Barber, M.D. et al. Transobturator tape compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 111, 611-21 (2008).
51. Barnes, N.M., Dmochowski, R.R., Park, R. & Nitti, V.W. Pubovaginal sling and pelvic prolapse repair in women with occult stress urinary incontinence: effect on postoperative emptying and voiding symptoms. Urology 59, 856-60 (2002).
52. Baumgartner, U., Magerl, W., Klein, T., Hopf, H.C. & Treede, R.D. Neurogenic hyperalgesia versus painful hypoalgesia: two distinct mechanisms of neuropathic pain. Pain 96, 141-51 (2002).
53. Beck, R.P. & Lai, A.R. Results in treating 88 cases of recurrent urinary stress incontinence with the Oxford fascia lata sling procedure. Am J Obstet Gynecol 142, 649-51 (1982).
54. Bekelman, J.E., Li, Y. & Gross, C.P. Scope and impact of financial conflicts of interest in biomedical research: a systematic review. JAMA 289, 454-65 (2003).
55. Benassi, G., Marconi, L., Accorsi, F., Angeloni, M. & Benassi, L. Abscess formation at the ischiorectal fossa 7 months after the application of a synthetic transobturator sling for stress urinary incontinence in a type II diabetic woman. Int Urogynecol J Pelvic Floor Dysfunct 18, 697-9 (2007).
56. Bendavid R, Lou W, Koch A, Iakovlev V, Mesh-Related SIN Syndrome. A Surreptitious Irreversible Neuralgia and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain, Int J Clin Med, vol. 5, pp. 799-810, 2014.
57. Bendavid R. Prostheses and Abdominal Wall Hernias. R.G. Landes Company 1994.
58. Bendavid, R. (1998). Complications of groin hernia surgery. Surg Clin North Am, 78(6), 1089-1103. doi: 10.1016/s0039-6109(05)70371-6
59. Bent, A., Ostergard, D. & Zwick-Zaffuto, M. Tissue reaction to expanded polytetrafluoroethylene suburethral sling for urinary incontinence: clinical and histologic study. Am J Obstet Gynecol 169, 1198-204 (1993).
60. Bertin, D., Leblanc, M., Marque, S. & Siri, D. Polypropylene degradation: Theoretical and experimental investigations. Polymer Degradation and Stability 95, 782–791 (2010).
61. Bianchi-Ferraro, A.M. et al. Single-incision sling compared with transobturator sling for treating stress urinary incontinence: a randomized controlled trial. Int Urogynecol J 24, 1459-65 (2013).

62. Biggs, G.Y., Ballert, K.N., Rosenblum, N. & Nitti, V. Patient-reported outcomes for tension-free vaginal tape-obturator in women treated with a previous anti-incontinence procedure. Int Urogynecol J Pelvic Floor Dysfunct 20, 331-5 (2009).
63. Birolini, C., Minossi, J., Lima, C., Utiyama, E. & Rasslan, S. Mesh cancer: long-term mesh infection leading to squamous-cell carcinoma of the abdominal wall. Hernia, Apr 19. [Epub ahead of print] (2013).
64. Blais, P., Carlsson, D., Clark, F., Sturgeon, P. & Wiles, D. The Photo-Oxidation of Polypropylene Monofilaments: Part II: Physical Changes and Microstructure. Textile Research Journal 46, 641-64 (1976).
65. Blaivas, J. & Mekel, G. Management of Urinary Fistulas Due to Midurethral Sling Surgery. J Urol, [Epub ahead of print] (2014).
66. Blaivas, J. (2004). Pubovaginal fascial sling for the treatment of all types of stress urinary incontinence: surgical technique and long-term outcome. Atlas of The Urologic Clinics, 12(2), 165-175. doi: 10.1016/j.auc.2004.07.003
67. Blaivas, J. et al. Salvage Surgery after Failed Treatment of Synthetic Mesh Sling Complications. J Urol 190, 1281-6 (2013).
68. Blaivas, J.G. & Jacobs, B.Z. Pubovaginal fascial sling for the treatment of complicated stress urinary incontinence. J Urol 145, 1214-8 (1991).
69. Blaivas, J.G. & Purohit, R.S. Post-traumatic female urethral reconstruction. Curr Urol Rep 9, 397-404 (2008).
70. Blaivas, J.G. et al. Management of urethral stricture in women. J Urol 188, 1778-82 (2012).
71. Blanchard, K. et al. Transponder-induced sarcoma in the heterozygous p53+/- mouse. Toxicol Pathol 27, 519-27 (1999).
72. Botros, S.M. et al. Detrusor overactivity and urge urinary incontinence following trans obturator versus midurethral slings. Neurourol Urodyn 26, 42-5 (2007).
73. Bringman S, Conze J, Cuccurullo D, Deprest J, Junge K, Klosterhalfen B, Parra-Davila E, Ramshaw B, Schumpelick V. Hernia repair: the search for ideal meshes. Hernia 2010; 14: 81-87.
74. Brito, L.M. et al. Comparison of the outcomes of the sling technique using a commercial and hand-made polypropylene sling. Int Braz J Urol 37, 519-27 (2011).
75. Brubaker, L., & Shull, B. (2012). A perfect storm. Int Urogynecol J, 23(1), 3-4. doi: 10.1007/s00192-011-1596-8
76. Brubaker, L., Norton, P. A., Albo, M. E., Chai, T. C., Dandreo, K. J., Lloyd, K. L., . . . Kusek, J. W. (2011). Adverse events over two years after retropubic or transobturator midurethral sling surgery: findings from the Trial of Midurethral Slings (TOMUS) study. Am J Obstet Gynecol, 205(5), 498 e491-496. doi: 10.1016/j.ajog.2011.07.011
77. Busby, G. & Broome, J. Necrotising fasciitis following unrecognised bladder injury during transobturator sling procedure. BJOG 114, 111-2 (2007).
78. But, I. & Pakiz, M. Irritative symptoms are the main predictor of satisfaction rate in women after transobturator tape procedures. Int Urogynecol J Pelvic Floor Dysfunct 20, 791-6 (2009).
79. Canete, P., Ortiz, E., Domingo, S. & Cano, A. Transobturator suburethral tape in the treatment of stress urinary incontinence: efficacy and quality of life after 5 year follow up. Maturitas 74, 166-71 (2013).
80. Carey, M., Higgs, P., Goh, J., Lim, J., Leong, A., Krause, H., & Cornish, A. (2009). Vaginal repair with mesh versus colporrhaphy for prolapse: a randomised controlled trial. BJOG, 116(10), 1380-1386. doi: 10.1111/j.1471-0528.2009.02254.x
81. Carminato, A., Vascellari, M., Marchioro, W., Melchiotti, E. & Mutinelli, F. Microchip-associated fibrosarcoma in a cat. Vet Dermatol 22, 565-9 (2011).
82. Carr, L.K. & Webster, G.D. Voiding dysfunction following incontinence surgery: diagnosis and treatment with retropubic or vaginal urethrolysis. J Urol 157, 821-3 (1997).

83. Castillo-Pino, E., Sasson, A. & Pons, J.E. Comparison of retropubic and transobturator tension-free vaginal implants for the treatment of stress urinary incontinence. Int J Gynaecol Obstet 110, 23-6 (2010).
84. Catts PF, Aroney M, Indyk JS. Med J Aust. Laparoscopic repair of inguinal hernia. 1994 Aug 15;161(4):242-5, 248.
85. Cetinel, B. & Tarcan, T. Management of complications after tension-free midurethral slings. Korean J Urol 54, 651-9 (2013).
86. Chae, H.D. et al. A comparative study of outside-in and inside-out transobturator tape procedures for stress urinary incontinence. Gynecol Obstet Invest 70, 200-5 (2010).
87. Chaikin, D.C., Rosenthal, J. & Blaivas, J.G. Pubovaginal fascial sling for all types of stress urinary incontinence: long-term analysis. J Urol 160, 1312-6 (1998).
88. Charalambous, S. et al. Transvaginal vs transobturator approach for synthetic sling placement in patients with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 19, 357-60 (2008).
89. Chen, H.Y., Ho, M., Hung, Y.C. & Huang, L.C. Analysis of risk factors associated with vaginal erosion after synthetic sling procedures for stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 19, 117-21 (2008).
90. Chen, X. et al. A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study. Arch Gynecol Obstet 284, 1461-6 (2011).
91. Chen, X., Li, H., Fan, B., Yang, X. & Tong, X. An inexpensive modified transobturator vaginal tape inside-out procedure for the surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 20, 1365-8 (2009).
92. Chene, G. et al. Long-term results of tension-free vaginal tape (TVT) for the treatment of female urinary stress incontinence. Eur J Obstet Gynecol Reprod Biol 134, 87-94 (2007).
93. Cheng, D. & Liu, C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. Eur J Obstet Gynecol Reprod Biol 161, 228-31 (2012).
94. Chiang HC, Chen PH, Chen YL, Yan MY, Chen CC, Lin J, Wang PF, Shih HJ. Inguinal hernia repair outcomes that utilized the modified Kugel patch without the optional onlay patch: a case series of 163 consecutive patients. Hernia. 2014 Aug 8. [Epub ahead of print]
95. Chin, Y. & Stanton, S. A follow up of silastic sling for genuine stress incontinence. Br J Obstet Gynaecol 102, 143-7 (1995).
96. Chmielewski, L., Walters, M. D., Weber, A. M., & Barber, M. D. (2011). Reanalysis of a randomized trial of 3 techniques of anterior colporrhaphy using clinically relevant definitions of success. Am J Obstet Gynecol, 205(1), 69 e61-68. doi: 10.1016/j.ajog.2011.03.027
97. Cho, M.K. et al. Comparison of the clinical and quality-of-life outcomes after the inside-out TVT-O procedure with or without concomitant transvaginal gynaecological surgery. J Obstet Gynaecol 32, 280-4 (2012).
98. Choe, J.M., Ogan, K. & Bennett, S. Antibacterial mesh sling: a prospective outcome analysis. Urology 55, 515-20 (2000).
99. Cholhan, H. J., Hutchings, T. B., & Rooney, K. E. (2010). Dyspareunia associated with paraurethral banding in the transobturator sling. Am J Obstet Gynecol, 202(5), 481 e481-485. doi: 10.1016/j.ajog.2010.01.061
100. Chughtai, B.I. et al. Midurethral Sling Is the Dominant Procedure for Female Stress Urinary Incontinence: Analysis of Case Logs From Certifying American Urologists. Urology 82, 1267-1271 (2013).
101. Clark, L., Clark, R. & Heber-Katz, E. A new murine model for mammalian wound repair and regeneration. Clin Immunol Immunopathol 88, 35-45 (1998).

102. Clave A, Yahi H, Hammou J, Montanari S, Gounon P, Clave H. Polypropylene as a reinforcement in pelvic surgery is not inert comparative analysis of 100 explants. Int Urogynecol J 2010; 21: 261-270.
103. Coda, A., Bendavid, R., Botto-Micca, F., Bossotti, M., & Bona, A. (2003). Structural alterations of prosthetic meshes in humans. Hernia: The Journal Of Hernias And Abdominal Wall Surgery, 7(1), 29-34.
104. Collinet, P. et al. The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. Int Urogynecol J Pelvic Floor Dysfunct 19, 711-5 (2008).
105. Connolly, T.P. Necrotizing surgical site infection after tension-free vaginal tape. Obstet Gynecol 104, 1275-6 (2004).
106. Cornel, E.B. & Vervest, H.A. Removal of a missed polypropylene tape by a combined transurethral and transabdominal endoscopic approach. Int Urogynecol J Pelvic Floor Dysfunct 16, 247-9 (2005).
107. Cornu, J.N. et al. Midterm prospective evaluation of TVT-Secur reveals high failure rate. Eur Urol 58, 157-61 (2010).
108. Corona, R., De Cicco, C., Schonman, R., Verguts, J., Ussia, A., & Koninckx, P. R. (2008). Tension-free Vaginal Tapes and Pelvic Nerve Neuropathy. J Minim Invasive Gynecol, 15(3), 262-267. doi: 10.1016/j.jmig.2008.03.006
109. Costantini, E. et al. Preoperative Valsalva leak point pressure may not predict outcome of mid-urethral slings. Analysis from a randomized controlled trial of retropubic versus transobturator mid-urethral slings. Int Braz J Urol 34, 73-81; discussion 81-3 (2008).
110. Costello CR, Bachman SL, Grant SA, Cleveland DS, Loy TS, Ranshaw BJ.Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Mesh Explants From a Single Patient. Surg Innov 2007: 14: 168-176.
111. Costello, C. R., Bachman, S. L., Ramshaw, B. J., & Grant, S. A. (2007). Materials characterization of explanted polypropylene hernia meshes. Journal of Biomedical Materials Research Part B: Applied Biomaterials, 83B(1), 44-49. doi: 10.1002/jbm.b.30764
112. Cozad M, Grant D, Bachman SL, Grant DN, Ramshaw BJ, Grant SA. Materials characterization of explanted polypropylene, polyethylene terephthalate and expanded polytetrafluoroethylene composites: Spectral and thermal analysis. J. Biomed Mater Res Part B: Appl Biomat 2010; 94B(2): 455-462.
113. Culligan, P. et al. Bacterial colony counts during vaginal surgery. Infect Dis Obstet Gynecol 11, 161-5 (2003).
114. Culligan, P. J., Littman, P. M., Salamon, C. G., Priestley, J. L., & Shariati, A. (2010). Evaluation of a transvaginal mesh delivery system for the correction of pelvic organ prolapse: subjective and objective findings at least 1 year after surgery. Am J Obstet Gynecol, 203(5), 506 e501-506. doi: 10.1016/j.ajog.2010.07.020
115. Dallenbach, P., Jungo Nancoz, C., Eperon, I., Dubuisson, J. B., & Boulvain, M. (2012). Incidence and risk factors for reoperation of surgically treated pelvic organ prolapse. Int Urogynecol J, 23(1), 35-41. doi: 10.1007/s00192-011-1483-3
116. Daneshgari, F., Kong, W. & Swartz, M. Complications of mid urethral slings: important outcomes for future clinical trials. J Urol 180, 1890-7 (2008).
117. Darai, E. et al. Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes. Eur Urol 51, 795-801; discussion 801-2 (2007).
118. Dati, S., De Lellis, V., Palermo, P., & Carta, G. (2010). A comparison between synthetic and biosynthetic meshes in the surgical treatment of severe genital prolapse: Results and complications. Urogynaecologia; Vol 23, No 3 (2009).

119. Davila, G. W., Drutz, H., & Deprest, J. (2006). Clinical implications of the biology of grafts: conclusions of the 2005 IUGA Grafts Roundtable. Int Urogynecol J Pelvic Floor Dysfunct, 17 Suppl 1, S51-55. doi: 10.1007/s00192-006-0099-5
120. Davis, N.F., Smyth, L.G., Giri, S.K. & Flood, H.D. Evaluation of endoscopic laser excision of polypropylene mesh/sutures following anti-incontinence procedures. J Urol 188, 1828-32 (2012).
121. de Carvalho CL, Silveira AF, Rosa Ddos S A study of the controlled degradation of polypropylene containing pro-oxidant agents. Springerplus. 2013 Nov 20;2:623.
122. de Tayrac, R., Alves, A., & Therin, M. (2007). Collagen-coated vs noncoated low-weight polypropylene meshes in a sheep model for vaginal surgery. A pilot study. Int Urogynecol J Pelvic Floor Dysfunct, 18(5), 513-520. doi: 10.1007/s00192-006-0176-9
123. de Tayrac, R., Devoldere, G., Renaudie, J., Villard, P., Guilbaud, O., & Eglin, G. (2007). Prolapse repair by vaginal route using a new protected low-weight polypropylene mesh: 1-year functional and anatomical outcome in a prospective multicentre study. Int Urogynecol J Pelvic Floor Dysfunct, 18(3), 251-256. doi: 10.1007/s00192-006-0135-5
124. de Tayrac, R., Eglin, G., Villard, P., Devoldere, G., Renaudie, J., & Guilbaud, O. (2008). Anatomical and functional assessment of prolapse repair by vaginal route using a collagen coating polypropylene mesh. A french prospective multicentre study. 3-year results. IUGA.
125. DeBord, J. R. (1998). The historical development of prosthetics in hernia surgery. Surgical Clinics of North America, 78(6), 973-1006. doi: http://dx.doi.org/10.1016/S0039-6109(05)70365-0
126. Deffieux, X. et al. Prepubic and thigh abscess after successive placement of two suburethral slings. Int Urogynecol J Pelvic Floor Dysfunct 18, 571-4 (2007).
127. Deffieux, X. et al. Transobturator TVT-O versus retropubic TVT: results of a multicenter randomized controlled trial at 24 months follow-up. Int Urogynecol J 21, 1337-45 (2010).
128. Delorme, E. [Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women]. Prog Urol 11, 1306-13 (2001).
129. Demirer, S., Kepenekci, I., Evirgen, O., Birsen, O., Tuzuner, A., Karahuseyinoglu, S., . . . Kuterdem, E. (2006). The effect of polypropylene mesh on ilioinguinal nerve in open mesh repair of groin hernia. The Journal Of Surgical Research, 131(2), 175-181.
130. Deng, D., Rutman, M., Raz, S. & Rodriguez, L. Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-reported? Neurourol Urodyn 26, 46-52 (2007).
131. Denis Bertin, Marie Leblanc, Sylvain R.A. Marque*, Didier Siri. Polypropylene degradation: Theoretical and experimental investigations. Polymer Degradation and Stability 95 (2010) 782-791
132. DEPO.ETH.MESH.00004755
133. Deposition of Dr. Thomas A. Barbolt (1/8/14)
134. DePrest J, Klosterhalfen B, Schreurs A, Verguts J, De Ridder D, Claerhout F. Clinicopathological Study of Patients Requiring Reinvention After Sacrocolpopexy With Xenogenic Acellular Collagen Grafts. J ofUrol 2010; 183:2249-2255.
135. Dindo, D., Demartines, N. & Clavien, P. Classification of Surgical Complications: A New Proposal With Evaluation in a Cohort of 6336 Patients and Results of a Survey. Ann Surg 240, 205-213 (2004).
136. Diwadkar, G. B., Barber, M. D., Feiner, B., Maher, C., & Jelovsek, J. E. (2009). Complication and reoperation rates after apical vaginal prolapse surgical repair: a systematic review. Obstet Gynecol, 113(2 Pt 1), 367-373. doi: 10.1097/AOG.0b013e318195888d
137. Djehdian, L.M. et al. Transobturator sling compared with single-incision mini-sling for the treatment of stress urinary incontinence: a randomized controlled trial. Obstet Gynecol 123, 553-61 (2014).

138. Dmochowski, R., Scarpero, H.M. & Starkman, J.S. in Campbell-Walsh urology (eds. Wein, A.J., Kavoussi, L.R., Novick, A.C., Partin, A.W. & Peters, C.A.) 2251-2272 (Saunders, Philadelphia, 2007).
139. Dmochowski, R.R. et al. Update of AUA guideline on the surgical management of female stress urinary incontinence. J Urol 183, 1906-14 (2010).
140. Dobson, A. et al. Trans-obturator surgery for stress urinary incontinence: 1-year follow-up of a cohort of 52 women. Int Urogynecol J Pelvic Floor Dysfunct 18, 27-32 (2007).
141. Domingo, S. et al. Transobturator tape procedure outcome: a clinical and quality of life analysis of a 1-year follow-up. Int Urogynecol J Pelvic Floor Dysfunct 18, 895-900 (2007).
142. Domingo, S., Alama, P., Ruiz, N., Perales, A. & Pellicer, A. Diagnosis, management and prognosis of vaginal erosion after transobturator suburethral tape procedure using a nonwoven thermally bonded polypropylene mesh. J Urol 173, 1627-30 (2005).
143. Duckett, J. & Constantine, G. Complications of silicone sling insertion for stress urinary incontinence. J Urol 163, 1835-7 (2000).
144. Dunn R.F., S. A. Guelcher, V. Iakovlev. Failure Analysis of Transvaginal Mesh Products – a Biomaterials Perspective Using Materials Science Fundamentals. 2014 AIChE Annual Meeting: 112f
145. Dunn, G.E. et al. Changed women: the long-term impact of vaginal mesh complications. Female Pelvic Med Reconstr Surg 20, 131-6 (2014).
146. Dyrkorn, O.A., Kulseng-Hanssen, S. & Sandvik, L. TVT compared with TVT-O and TOT: results from the Norwegian National Incontinence Registry. Int Urogynecol J 21, 1321-6 (2010).
147. Eandi, J.A., Tanaka, S.T., Hellenthal, N.J., O'Connor, R.C. & Stone, A.R. Self-reported urinary continence outcomes for repeat midurethral synthetic sling placement. Int Braz J Urol 34, 336-42; discussion 343-4 (2008).
148. Ek, M., Tegerstedt, G., Falconer, C., Kjaeldgaard, A., Rezapour, M., Rudnicki, M., & Altman, D. (2010). Urodynamic assessment of anterior vaginal wall surgery: a randomized comparison between colporraphy and transvaginal mesh. Neurourol Urodyn, 29(4), 527-531. doi: 10.1002/nau.20811
149. Ellington, D. & Richter, H. Indications, contraindications, and complications of mesh in surgical treatment of pelvic organ prolapse. Clin Obstet Gynecol 56, 276-88 (2013).
150. Elliott, D. S. (2012). Con: mesh in vaginal surgery: do the risks outweigh the benefits? Curr Opin Urol, 22(4), 276-281. doi: 10.1097/MOU.0b013e3283545991
151. Elliott, J.E. & Maslow, K.D. Remote discovery of an asymptomatic bowel perforation by a mid-urethral sling. Int Urogynecol J 23, 243-5 (2012).
152. Elliott, M. & Juler, G. Comparison of Marlex mesh and microporous teflon sheets when used for hernia repair in the experimental animal. Am J Surg 137, 342-4 (1979).
153. Elmer, C., Blomgren, B., Falconer, C., Zhang, A. & Altman, D. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery. J Urol 181, 1189-95 (2009).
154. Errando, C., Batista, J.E. & Arano, P. Polytetrafluoroethylene sling for failure in female stress incontinence surgery. World J Urol 14 Suppl 1, S48-50 (1996).
155. Estevez, J.P., Cosson, M. & Boukerrou, M. An uncommon case of urethrovaginal fistula resulting from tension-free vaginal tape. Int Urogynecol J 21, 889-91 (2010).
156. ETH.MESH.15955438-15955473
157. ETH.MESH.11336474
158. ETH.MESH.09888187
159. ETH.MESH.13334286
160. FDA Public Health Notification: Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence (2008).

161. FDA: Surgical placement of mesh to repair pelvic organ prolapse poses risks. (2011) FDA News Release.
162. Feiner, B. & Maher, C. Vaginal mesh contraction: definition, clinical presentation, and management. Obstet Gynecol 115, 325-30 (2010).
163. Felix EL, Harbertson N, Vartanian S.Surg Endosc. Laparoscopic hernioplasty: significant complications. 1999 Apr;13(4):328-31.
164. Feng, C.L., Chin, H.Y. & Wang, K.H. Transobturator vaginal tape inside out procedure for stress urinary incontinence: results of 102 patients. Int Urogynecol J Pelvic Floor Dysfunct 19, 1423-7 (2008).
165. Fialkow, M.F., Lentz, G.M., Miller, E.A. & Miller, J.L. Complications from transvaginal pubovaginal slings using bone anchor fixation. Urology 64, 1127-32 (2004).
166. Foon, R., Toozs-Hobson, P., & Latthe, P. M. (2008). Adjuvant materials in anterior vaginal wall prolapse surgery: a systematic review of effectiveness and complications. Int Urogynecol J Pelvic Floor Dysfunct, 19(12), 1697-1706. doi: 10.1007/s00192-008-0668-x
167. Fornasari D. Pain mechanisms in patients with chronic pain. Clin Drug Investig.2012 Feb;32 Suppl 1:45-52.
168. Fourie, T. & Cohen, P.L. Delayed bowel erosion by tension-free vaginal tape (TVT). Int Urogynecol J Pelvic Floor Dysfunct 14, 362-4 (2003).
169. Frederick, R.W., Carey, J.M. & Leach, G.E. Osseous complications after transvaginal bone anchor fixation in female pelvic reconstructive surgery: report from single largest prospective series and literature review. Urology 64, 669-74 (2004).
170. Freeman, R. et al. What patients think: patient-reported outcomes of retropubic versus trans-obturator mid-urethral slings for urodynamic stress incontinence--a multi-centre randomised controlled trial. Int Urogynecol J 22, 279-86 (2011).
171. Frostling, H. et al. Analytical, occupational and toxicologic aspects of the degradation products of polypropylene plastics. Scand J Work Environ Health 10, 163-169 (1984).
172. Frostling, H., Hoff, A., Jacobsson, S., Pfaffli, P., Vainiotalo, S., & Zitting, A. (1984). Analytical, occupational and toxicologic aspects of the degradation products of polypropylene plastics. Scand J Work Environ Health, 10(3), 163-169.
173. Gandhi, S., Abramov, Y., Kwon, C., Beaumont, J. L., Botros, S., Sand, P. K., & Goldberg, R. P. (2006). TVT versus SPARC: comparison of outcomes for two midurethral tape procedures. Int Urogynecol J Pelvic Floor Dysfunct, 17(2), 125-130. doi: 10.1007/s00192-005-1369-3
174. Garcia-Urena, M.A. et al. Differences in polypropylene shrinkage depending on mesh position in an experimental study. Am J Surg 193, 538-42 (2007).
175. Giberti, C., Gallo, F., Cortese, P. & Schenone, M. The suburethral tension adjustable sling (REMEEX system) in the treatment of female urinary incontinence due to 'true' intrinsic sphincter deficiency: results after 5 years of mean follow-up. BJU Int 108, 1140-4 (2011).
176. Glavind, K. & Larsen, T. Long-term follow-up of intravaginal slingplasty operation for urinary stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 19, 1081-3 (2008).
177. Goktolga, U. et al. Tension-free vaginal tape for surgical relief of intrinsic sphincter deficiency: results of 5-year follow-up. J Minim Invasive Gynecol 15, 78-81 (2008).
178. Gold, R.S., Groutz, A., Pauzner, D., Lessing, J. & Gordon, D. Bladder perforation during tension-free vaginal tape surgery: does it matter? J Reprod Med 52, 616-8 (2007).
179. Goldman, H. B., & Petros, P. E. (2012). Post-Implantation Alterations of Polypropylene in the Human. J Urol. doi: 10.1016/j.juro.2012.11.155
180. Goldman, H.B. Large thigh abscess after placement of synthetic transobturator sling. Int Urogynecol J Pelvic Floor Dysfunct 17, 295-6 (2006).
181. Goldman, H.B. Simple sling incision for the treatment of iatrogenic urethral obstruction. Urology 62, 714-8 (2003).

182. Gonzalez, R. & Ramshaw, B. Comparison of tissue integration between polyester and polypropylene prostheses in the preperitoneal space. Am Surg 69, 471-6; discussion 476-7 (2003).
183. Govier, F. et al. Complications of transvaginal silicone-coated polyester synthetic mesh sling. Urology 66, 741-5 (2005).
184. Groutz, A. et al. Ten-year subjective outcome results of the retropubic tension-free vaginal tape for treatment of stress urinary incontinence. J Minim Invasive Gynecol 18, 726-9 (2011).
185. Groutz, A. et al. The safety and efficacy of the inside-out trans-obturator TVT in elderly versus younger stress-incontinent women: A prospective study of 353 consecutive patients. Neurourology and Urodynamics 30, 380-383 (2011).
186. Groutz, A., Rosen, G., Gold, R., Lessing, J.B. & Gordon, D. Long-term outcome of transobturator tension-free vaginal tape: efficacy and risk factors for surgical failure. J Womens Health (Larchmt) 20, 1525-8 (2011).
187. Gruber, D.D., Wiersma, D.S., Dunn, J.S., Meldrum, K.A. & Krivak, T.C. Cecal perforation complicating placement of a transvaginal tension-free vaginal tape. Int Urogynecol J Pelvic Floor Dysfunct 18, 671-3 (2007).
188. Guerrero, K.L. et al. A randomised controlled trial comparing TVT, Pelvicol and autologous fascial slings for the treatment of stress urinary incontinence in women. BJOG 117, 1493-502 (2010).
189. Gulino G, Antonucci M, Palermo G, Sasso F, Tienforti D, D'Addessi A, Bassi PF.Urological complications following inguinal hernioplasty. Arch Ital Urol Androl. 2012 Sep;84(3):105-10.
190. H. Azizi, I. Ghasemi, M. Karrabi, Controlled-peroxide degradation of polypropylene: Rheological properties and prediction of MWD from rheological data, Polymer Testing 27 (2008): 548–554
191. Haliloglu, B., Karateke, A., Coksuer, H., Peker, H. & Cam, C. The role of urethral hypermobility and intrinsic sphincteric deficiency on the outcome of transobturator tape procedure: a prospective study with 2-year follow-up. Int Urogynecol J 21, 173-8 (2010).
192. Hamouda, A., Kennedy, J., Grant, N., Nigam, A. & Karanjia, N. Mesh erosion into the urinary bladder following laparoscopic inguinal hernia repair; is this the tip of the iceberg? Hernia 14, 317-9 (2010).
193. Hansen, B.L., Dunn, G.E., Norton, P., Hsu, Y. & Nygaard, I. Long-term follow-up of treatment for synthetic mesh complications. Female Pelvic Med Reconstr Surg 20, 126-30 (2014).
194. Haylen, B. et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) Joint Terminology and Classification of the Complications Related Directly to the Insertion of Prosthesis (Meshes, Implants, Tapes) and Grafts in Female Pelvic Flo. Neurourol Urodynam 30, 2-12 (2011).
195. Heinonen, P., Ala-Nissila, S., Raty, R., Laurikainen, E. & Kiilholma, P. Objective cure rates and patient satisfaction after the transobturator tape procedure during 6.5-year follow-up. J Minim Invasive Gynecol 20, 73-8 (2013).
196. Hellberg, D., Holmgren, C., Lanner, L. & Nilsson, S. The very obese woman and the very old woman: tension-free vaginal tape for the treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 18, 423-9 (2007).
197. Hinoul, P., Bonnet, P., Krofta, L., Waltregny, D. & de Leval, J. An anatomic comparison of the original versus a modified inside-out transobturator procedure. Int Urogynecol J 22, 997-1004 (2011).
198. Hirose, T. et al. Randomized clinical trial comparing lightweight or heavyweight mesh for mesh plug repair of primary inguinal hernia. Hernia 18, 213-9 (2014).
199. Hodroff, M., Portis, A. & Siegel, S.W. Endoscopic removal of intravesical polypropylene sling with the holmium laser. J Urol 172, 1361-2 (2004).

200. Hodroff, M.A., Sutherland, S.E., Kesha, J.B. & Siegel, S.W. Treatment of stress incontinence with the SPARC sling: intraoperative and early complications of 445 patients. Urology 66, 760-2 (2005).
201. Holmgren, C., Nilsson, S., Lanner, L. & Hellberg, D. Frequency of de novo urgency in 463 women who had undergone the tension-free vaginal tape (TVT) procedure for genuine stress urinary incontinence--a long-term follow-up. Eur J Obstet Gynecol Reprod Biol 132, 121-5 (2007).
202. Hom, D., Desautel, M.G., Lumerman, J.H., Feraren, R.E. & Badlani, G.H. Pubovaginal sling using polypropylene mesh and Vesica bone anchors. Urology 51, 708-13 (1998).
203. Hopkins, M.P. & Rooney, C. Entero mesh vaginal fistula secondary to abdominal sacral colpopexy. Obstet Gynecol 103, 1035-6 (2004).
204. Hota, L.S. et al. TVT-Secur (Hammock) versus TVT-Obturator: a randomized trial of suburethral sling operative procedures. Female Pelvic Med Reconstr Surg 18, 41-5 (2012).
205. Hou, J.C., Alhalabi, F., Lemack, G.E. & Zimmern, P.E. Outcome of transvaginal mesh and tape removed for pain only. J Urol 192, 856-60 (2014).
206. Houwert, R.M., Renes-Zijl, C., Vos, M.C. & Vervest, H.A. TVT-O versus Monarc after a 2-4-year follow-up: a prospective comparative study. Int Urogynecol J Pelvic Floor Dysfunct 20, 1327-33 (2009).
207. Huffaker, R.K., Yandell, P.M. & Shull, B.L. Tension-free vaginal tape bowel perforation. Int Urogynecol J 21, 251-3 (2010).
208. Hullfish, K. L., Bovbjerg, V. E., Gibson, J., & Steers, W. D. (2002). Patient-centered goals for pelvic floor dysfunction surgery: what is success, and is it achieved? Am J Obstet Gynecol, 187(1), 88-92.
209. Huwyler, M., Springer, J., Kessler, T.M. & Burkhard, F.C. A safe and simple solution for intravesical tension-free vaginal tape erosion: removal by standard transurethral resection. BJU Int 102, 582-5 (2008).
210. "IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS," [Online]. Available: http://monographs.iarc.fr/ENG/Monographs/vol74/index.php. [Accessed 24 July 2014].
211. Iakovlev V, Guelcher S, Bendavid R. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35
212. Iakovlev V, Mekel G, Blaivas J. Pathological Findings of Transvaginal Polypropylene Slings explanted for Late Complications: Mesh is Not Inert. International Continence Society (ICS) annual meeting, 2014: 228.
213. Iakovlev V, S. Guelcher, R. Bendavid. In Vivo Degradation of Surgical Polypropylene Meshes: A Finding Overlooked for Decades. Virchows Archiv 2014, 463(1): 35
214. Iakovlev V. Explanted Surgical Meshes: What Pathologists and Industry Failed to do for 50 Years. Virchows Archiv 2014, 463(1): 337
215. Iakovlev V., E. Carey, J, Steege. Pathology of Explanted Transvaginal Meshes. International Journal of Medical, Health, Pharmaceutical and Biomedical Engineering, 2014, 8(9): 510-13.
216. Iakovlev V.V., E. T. Carey, G. Iakovleva, J. Steege, R. Bendavid. Pathological findings associated with pain in transvaginal meshes. The 20th World Congress on Controversies in Obstetrics, Gynecology & Infertility (COGI), 2014.
217. Iakovlev VV, Carey ET, Steege J. Pathology of Explanted Transvaginal Meshes. World Academy of Science Engineering and Technology, 2014 in press.
218. Iglesia, C. B., Sokol, A. I., Sokol, E. R., Kudish, B. I., Gutman, R. E., Peterson, J. L., & Shott, S. (2010). Vaginal mesh for prolapse: a randomized controlled trial. Obstet Gynecol, 116(2 Pt 1), 293-303. doi: 10.1097/AOG.0b013e3181e7d7f8
219. Ivam Damjanov, Histopathology, Williams and Wilkins, 1996.

220. Jacquetin, B. & Cosson, M. Complications of vaginal mesh: our experience. Int Urogynecol J Pelvic Floor Dysfunct 20, 893-6 (2009).
221. Jakimiuk, A.J. et al. Surgical treatment of stress urinary incontinence using the tension-free vaginal tape-obturator system (TVT-O) technique. Eur J Obstet Gynecol Reprod Biol 135, 127-31 (2007).
222. Jeon, M.J. et al. Surgical therapeutic index of tension-free vaginal tape and transobturator tape for stress urinary incontinence. Gynecol Obstet Invest 65, 41-6 (2008).
223. Jerabek, J. et al. Evaluation of three purely polypropylene meshes of different pore sizes in an onlay position in a New Zealand white rabbit model. Hernia, epub ahead of print (2014).
224. Jerabek, J. et al. Evaluation of three purely polypropylene meshes of different pore sizes in an onlay position in a New Zealand white rabbit model. Hernia, epub ahead of print (2014).
225. Jia, X., Glazener, C., Mowatt, G., MacLennan, G., Bain, C., Fraser, C., & Burr, J. (2008). Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG, 115(11), 1350-1361. doi: 10.1111/j.1471-0528.2008.01845.x
226. Jijon, A., Hegde, A., Arias, B., Aguilar, V. & Davila, G.W. An inelastic retropubic suburethral sling in women with intrinsic sphincter deficiency. Int Urogynecol J 24, 1325-30 (2013).
227. Johner, A., Faulds, J. & Wiseman, S. Planned ilioinguinal nerve excision for prevention of chronic pain after inguinal hernia repair: a meta-analysis. Surgery 150, 534-41 (2011).
228. Johnson, D.W., ElHajj, M., EL, O.B.-B., Miller, H.J. & Fine, P.M. Necrotizing fasciitis after tension-free vaginal tape (TVT) placement. Int Urogynecol J Pelvic Floor Dysfunct 14, 291-3 (2003).
229. Jongebloed, W. & Worst, J. Degradation of polypropylene in the human eye: a SEM-study. Advances In Ophthalmology 64, 143-152 (1986).
230. Jonsson Funk, M., Siddiqui, N.Y., Pate, V., Amundsen, C.L. & Wu, J.M. Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. Am J Obstet Gynecol 208, 73 e1-7 (2013).
231. Jonsson, M., Siddiqui, N., Pate, V., Amundsen, C. & Wu, J. Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. Am J Obstet Gynecol 208, 73-85 (2013).
232. Juma, S. & Brito, C.G. Transobturator tape (TOT): Two years follow-up. Neurourol Urodyn 26, 37-41 (2007).
233. Junge K, Klinge U, Klosterhalfen B, Mertens PR, Rosch R, Schachtrupp A, Ulmer F, Schumpelick V. Influence of Mesh Materials on Collagen Deposition in a Rat Model. J Invest Surg 2002; 15: 319-328.
234. Junge K, Klinge U, Rosch R, Klosterhalfen B, Schumpelick V. Functional and Morphologic Properties of a Modified Mesh for Inguinal Hernia Repair. World J Surg 2002; 26:1472-1480.
235. Junge K, Rosch R, Bialasinski L, Klinge U, Klosterhalfen B, Schumpelick V. Persistent Extracellular Matrix Remodeling at the Interface to Polymers Used for Hernia Repair. Eur Surg Res 2003; 35: 497-504.
236. Junge, K. et al. Persistent extracellular matrix remodelling at the interface to polymers used for hernia repair. Eur Surg Res 35, 497-504 (2003).
237. Kaelin-Gambirasio, I., Jacob, S., Boulvain, M., Dubuisson, J.B. & Dallenbach, P. Complications associated with transobturator sling procedures: analysis of 233 consecutive cases with a 27 months follow-up. BMC Womens Health 9, 28 (2009).
238. Kang, M.B., Kim, H.G., Paick, S.H., Lho, Y.S. & Park, H.K. Intraoperative maximal urethral closing pressure measurement: a new technique of tape tension adjustment in transobturator sling surgery? Int Braz J Urol 37, 751-7 (2011).

239. Kapoor, D. S., Nemcova, M., Pantazis, K., Brockman, P., Bombieri, L., & Freeman, R. M. (2010). Reoperation rate for traditional anterior vaginal repair: analysis of 207 cases with a median 4-year follow-up. Int Urogynecol J, 21(1), 27-31. doi: 10.1007/s00192-009-0991-x
240. Karabulut, A., Demitas, O. & Gok, S. A late complication of transobturator tape procedure: vaginocutaneous fistula formation with vaginal mesh erosion. Int Urogynecol J 25, 559-61 (2014).
241. Karateke, A., Haliloglu, B., Cam, C. & Sakalli, M. Comparison of TVT and TVT-O in patients with stress urinary incontinence: short-term cure rates and factors influencing the outcome. A prospective randomised study. Aust N Z J Obstet Gynaecol 49, 99-105 (2009).
242. Karram, M.M., Segal, J.L., Vassallo, B.J. & Kleeman, S.D. Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol 101, 929-32 (2003).
243. Kascak, P.K., B. Fatal Injury of the Small Intestine during Retropubic Sling Placement - A Case Report. Obstetrics and Gynaecology Cases - Reviews 1 (2014).
244. Kavvadias, T., Kaemmer, D., Klinge, U., Kuschel, S. & Schuessler, B. Foreign body reaction in vaginally eroded and noneroded polypropylene suburethral slings in the female: a case series. Int Urogynecol J Pelvic Floor Dysfunct 20, 1473-6 (2009).
245. Kawasaki, A. et al. Comparing the risk of urethrolysis for the treatment of voiding dysfunction between two retropubic mesh slings: a case-control study. Int Urogynecol J 24, 589-94 (2013).
246. Keisha A. Jones, Andrew Feola, Leslie Meyn, Steven D. Abramowitch, Pamela A. Moalli Tensile Properties of Commonly Used Prolapse Meshes Int Urogynecol J Pelvic Floor Dysfunct. 2009 July; 20(7): 847–853
247. Keys, T., Aboushwareb, T. & Badlani, G. Re: post-implantation alterations of polypropylene in the human. J Urol 189, 1996-2000 (2013).
248. Khan, L.R., Kumar, S. & Nixon, S.J. Early results for new lightweight mesh in laparoscopic totally extra-peritoneal inguinal hernia repair. Hernia 10, 303-8 (2006).
249. Kidd BL, Urban LA. Mechanisms of inflammatory pain. Br J Anaesth. 2001 Jul;87(1):3-11
250. Kidd, B. & Urban, L. Mechanisms of inflammatory pain. Br J Anaesth 87, 3-11 (2001).
251. Killingsworth, L.B. et al. One-year outcomes of tension-free vaginal tape (TVT) mid-urethral slings in overweight and obese women. Int Urogynecol J Pelvic Floor Dysfunct 20, 1103-8 (2009).
252. Kim, J., Lucioni, A., Govier, F. & Kobashi, K. Worse long-term surgical outcomes in elderly patients undergoing SPARC retropubic midurethral sling placement. BJU Int 108, 708-12 (2011).
253. Kim, J.C. et al. A safety and quality of life analysis of intravaginal slingplasty in female stress incontinence: a prospective, open label, multicenter, and observational study. Int Urogynecol J Pelvic Floor Dysfunct 18, 1331-5 (2007).
254. Kim, J.H., Doo, S.W., Yang, W.J. & Song, Y.S. Laparoscopic transvesical excision and reconstruction in the management of mid-urethral tape mesh erosion and stones around the bladder neck: initial experiences. BJU Int 110, E1009-13 (2012).
255. King, R. N., & Lyman, D. J. (1975). Polymers in contact with the body. Environmental health perspectives, 11, 71-74.
256. Klein B, Schiffer R, Hafemann B, Klosterhalfen B, Zwaldo-Klarwasser G.Inflammatory response to a porcine membrane composed of fibrous collagen and elastin as dermal substitute. J Materials Sci: Materials 'Med 2001; 12: 419-424.
257. Klinge U, Conze J, Klosterhalfen B, Limberg W, Obolenski B, Ottinger AP, Schumpelick V. Alteration of Abomdinal Wall Mechanics after Mesh Implantation. Langenbecks Arch Chir 1996; 381: 323-332.
258. Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B Schumpelick V. Do Multifilament Alloplastic Meshes Increase the Infection Rate? Analysis of the Polymeric Surface,

the Bacteria Adherence, and the In Vivo Consequences in a Rat Model. J Biomed Mater Res 2002; 63:765-771.

259. Klinge U, Junge K, Stumpf M, Ottinger AP, Klosterhalfen B. Functional and Morphological Evaluation of a Low-Weight, Monofilament Polypropylene Mesh for Hernia Repair. J Biomed Mater Res 2002; 63:129-136.

260. Klinge U, Klink CD, Klosterhalfen B. The Ideal Mesh- More than a Mosquito Net. Zentralbl Chir 2010; 135(2): 168-174.

261. Klinge U, Klosterhalfen B, Birkenhauer V, Junge K, Conze J, Schumpelick V. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. J Surg Res 2002; 103: 208-214.

262. Klinge U, Klosterhalfen B, Conze J, Limberg W,Obolenski B, Ottinger AP, Schumpelick V. Modified Mesh for Hernia Repair that is Adapted to the Physiology of the Abdominal Wall. Eur J Surg 1998; 164: 951-960.

263. Klinge U, Klosterhalfen B, Mueller M, Ottinger AP, Schumpelick V. Shrinking of Polypropylene Mesh in vivo: An Experimental Study in Dogs. Eur J Surg 1998; 164: 965-969.

264. Klinge U, Klosterhalfen B, Muller M, Anurov M, Ottinger A, Schumpelick V. Influence of polyglactincoating on functional and morphological parameters of polypropylene-mesh modifications for abdominal wall repair. Biomaterials 1999; 20: 613-623.

265. Klinge U, Klosterhalfen B, Muller M, Schumpelick V. Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. Eur J Surg 1999; 165:665- 673.

266. Klinge U, Klosterhalfen B. Modified classification of surgical meshes for hernia repair based on the analyses of 1,000 explanted meshes. Hernia 20 12.

267. Klinge U, Schumpelick V, Klosterhalfen B. Functional assessment and tissue response of short- and longterm absorbable surgical meshes. Biomaterials 2001; 22: 1415-1424.

268. Klinge, U. et al. Impact of polymer pore size on the interface scar formation in a rat model. J Surg Res 103, 208-14 (2002).

269. Klinge, U., Klosterhalfen, B., Muller, M. & Schumpelick, V. Foreign Body Reaction to Meshes Used for the Repair of Abdominal Wall Hernias. Eur J Surg 165, 665- 673 (1999).

270. Klinge, U., Klosterhalfen, B., Müller, M., Ottinger, A. & Schumpelick, V. Shrinking of polypropylene mesh in vivo: an experimental study in dogs. Eur J Surg 164, 965-9 (1998).

271. C.D. Klink, K. Junge, M. Binnebosel, H. P. Alizai, J. Otto, U. P. Neumann, U. Klinge, Comparison of Long-Term Biocompability of PVDF and PP Meshes, *Journal of Investigative Surgery*, 24 (2011) 292-299.

272. Klosterhalfen B, Hermanns B, Rosch R, Junge K. Biological Response to Mesh. Eur Surg 2003; 3 5(1):16-20.

273. Klosterhalfen B, Junge K, Hermanns B, Klinge U. Influence of implantation interval on the long-term biocompatibility of surgical mesh. Brit J Surg 2002 89:1043-1048.

274. Klosterhalfen B, Junge K, Klinge U. The lightweight and large porous mesh concept for hernia repair. Expert Rev. Med. Devices 2005; 2(1): 1-15.

275. Klosterhalfen B, Klinge U, Hermanns B, Schumpelick V. Pathology of traditional surgical nets for hernia repair after long-term implantation in humans. Chirurg 2000; 71:43-51.

276. Klosterhalfen B, Klinge U, Schumpelick V. Functional and morphological evaluation of different polypropylene-mesh modifications for abdominal wall repair. Biomaterials 1998; 19:2235-2246.

277. Klosterhalfen, B. & Klinge, U. Retrieval study at 623 human mesh explants made of polypropylene--impact of mesh class and indication for mesh removal on tissue reaction. J Biomed Mater Res B Appl Biomater 101, 1393-9 (2013).

278. Klosterhalfen, B., Junge, K. & Klinge, U. The lightweight and large porous mesh concept for hernia repair. Expert Rev Med Devices 2, 103-17 (2005).

279. Klosterhalfen, B., Junge, K., Hermanns, B. & Klinge, U. Influence of implantation interval on the long-term biocompatibility of surgical mesh. Br J Surg 89, 1043-8 (2002).

280. Klutke, C. et al. Urinary retention after tension-free vaginal tape procedure: incidence and treatment. Urology 58, 697-701 (2001).
281. Kobashi, K.C. & Govier, F.E. Management of vaginal erosion of polypropylene mesh slings. J Urol 169, 2242-3 (2003).
282. Kobashi, K.C. et al. Erosion of woven polyester pubovaginal sling. J Urol 162, 2070-2 (1999).
283. Kociszewski, J. et al. Tape functionality: position, change in shape, and outcome after TVT procedure--mid-term results. Int Urogynecol J 21, 795-800 (2010).
284. Kocjancic, E. et al. Transobturator tape in the management of female stress incontinence: clinical outcomes at medium term follow-up. Urol Int 80, 275-8 (2008).
285. Kokanali, M. et al. Risk factors for mesh erosion after vaginal sling procedures for urinary incontinence. Eur J Obstet Gynecol Reprod Biol 177, 146-50 (2014).
286. Kramer DB, Xu S, Kesselheim AS. Regulation of Medical Devices in the United States and European Union. N Engl J Med 2012; 366(9): 848-855.
287. Kristensen, I. et al. Complications of the tension-free vaginal tape procedure for stress urinary incontinence. Int Urogynecol J 21, 1353-7 (2010).
288. Kudish, B. I., & Iglesia, C. B. (2010). Posterior wall prolapse and repair. Clin Obstet Gynecol, 53(1), 59-71. doi: 10.1097/GRF.0b013e3181cd41e3
289. Kumar, V., Abbas, A., Fausto, N. & Aster, J. Robbins and Cotran Pathological Basis of Disease, 8th Edition (Elsevier, Imprint: W.B. Saunders, 2010).
290. Kuo, H.C. Long-term surgical results of pubovaginal sling procedure using polypropylene mesh in the treatment of stress urinary incontinence. Urol Int 74, 147-52 (2005).
291. Kuuva, N. & Nilsson, C.G. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 81, 72-7 (2002).
292. Kwon, S., Latchamsetty, K., Benson, J. & Carreno, M. Inflammatory myofibroblastic tumor of the urinary tract following a TVT. Journal of Pelvic Medicine and Surgery 18, 249-51 (2012).
293. Langhans, T. Ueber Riesenzellen mit wandständigen Kernen in Tuberkeln und die fibröse Form des Tuberkels. Virchows Arch. Pathol. Anat. 42, 382–404 (1868).
294. Laskin, D. & Pendino, K. Macrophages and inflammatory mediators in tissue injury. Annu Rev Pharmacol Toxicol 35, 655-77 (1995).
295. Latthe, P., Foon, R. & Toozs-Hobson, P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 114, 522-531 (2007).
296. Latthe, P.M., Patodi, M. & Constantine, G. Transobturator tape procedure in stress urinary incontinence: UK experience of a district general hospital. J Obstet Gynaecol 27, 177-80 (2007).
297. Latthe, P.M., Singh, P., Foon, R. & Toozs-Hobson, P. Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. BJU Int 106, 68-76 (2010).
298. Lau, H.H., Su, T.H., Su, C.H., Lee, M.Y. & Sun, F.J. Short-term impact of tension-free vaginal tape obturator procedure on sexual function in women with stress urinary incontinence. J Sex Med 7, 1578-84 (2010).
299. Lee, D., Dillon, B., Lemack, G., Gomelsky, A. & Zimmern, P. Transvaginal mesh kits--how serious are the complications and are they reversible? Urology 81, 43-8 (2013).
300. Lee, H.N. et al. Transurethral injection of bulking agent for treatment of failed mid-urethral sling procedures. Int Urogynecol J 21, 1479-83 (2010).
301. Lee, J.H. et al. Modified transobturator tape (canal transobturator tape) surgery for female stress urinary incontinence. J Urol 181, 2616-21 (2009).
302. Lee, J.K., Agnew, G. & Dwyer, P.L. Mesh-related chronic infections in silicone-coated polyester suburethral slings. Int Urogynecol J 22, 29-35 (2011).

303. Lee, K.S. et al. Outcomes following repeat mid urethral synthetic sling after failure of the initial sling procedure: rediscovery of the tension-free vaginal tape procedure. J Urol 178, 1370-4; discussion 1374 (2007).
304. Lee TW, Tumanov S, Villas-Bôas SG, Montgomery JM, Birch NP. Chemicals eluting from disposable plastic syringes and syringe filters alter neurite growth, axogenesis and the microtubule cytoskeleton in cultured hippocampal neurons. J Neurochem 2014;Dec 18[Epub ahead of print]:doi: 10.1111/jnc.13009.
305. Lee, U., Wolff, E. M., & Kobashi, K. C. (2012). Native tissue repairs in anterior vaginal prolapse surgery: examining definitions of surgical success in the mesh era. Curr Opin Urol, 22(4), 265-270. doi: 10.1097/MOU.0b013e32835459bb
306. Lefranc, O., Bayon, Y., Montanari, S., Gravagna, P., & Thérin, M. (2011). Reinforcement Materials in Soft Tissue Repair: Key Parameters Controlling Tolerance and Performance – Current and Future Trends in Mesh Development. In P. Theobald, C. W. Zimmerman & G. W. Davila (Eds.), New Techniques in Genital Prolapse Surgery (Vol. 5, pp. 275-287): Springer London.
307. Levinson SR,Luo S,Henry MA.The role of sodium channels in chronic pain. Muscle Nerve. 2012 Aug;46 (2):155-65.
308. Li, B., Zhu, L., Lang, J., Fan, R. & Xu, T. Long-term Outcomes of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence: 7-Year Follow-up in China. J Minim Invasive Gynecol 19, 201-205 (2012).
309. Liapis, A., Bakas, P. & Creatsas, G. Efficacy of inside-out transobturator vaginal tape (TVTO) at 4 years follow up. Eur J Obstet Gynecol Reprod Biol 148, 199-201 (2010).
310. Liebert, T., Chartoff, R., Cosgrove, S. & McCuskey, R. Subcutaneous implants of polypropylene filaments. Journal of Biomedical Materials Research, Part A 10, 939–951 (1976).
311. Lier, D. et al. Trans-obturator tape compared with tension-free vaginal tape in the surgical treatment of stress urinary incontinence: a cost utility analysis. BJOG 118, 550-6 (2011).
312. Lim, J., Cornish, A. & Carey, M.P. Clinical and quality-of-life outcomes in women treated by the TVT-O procedure. BJOG 113, 1315-20 (2006).
313. Lim, Y.N. et al. Do the Advantage slings work as well as the tension-free vaginal tapes? Int Urogynecol J 21, 1157-62 (2010).
314. Linderoth, G., Kehlet, H., Aasvang, E. K., & Werner, M. U. (2011). Neurophysiological characterization of persistent pain after laparoscopic inguinal hernia repair. Hernia, 15(5), 521-529. doi: 10.1007/s10029-011-0815-z
315. Linley JE, Rose K, Ooi L, Gamper NUnderstanding inflammatory pain: ion channels contributing to acute and chronic nociception. Pflugers Arch. 2010 Apr; 459(5):657-69.
316. Lintin, L.A. & Kingsnorth, A.N. Mechanical failure of a lightweight polypropylene mesh. Hernia 18, 131-3 (2014).
317. Littman, P. M., & Culligan, P. J. (2009). The Rapid Evolution of Vaginal Mesh Delivery Systems for the Correction of Pelvic Organ Prolapse: Part I. The Female Patient, 34, 2-8.
318. Litwin DE, Pham QN, Oleniuk FH, Kluftinger AM, Rossi L.Laparoscopic groin hernia surgery: the TAPP procedure. Transabdominal preperitoneal hernia repair. Can J Surg. 1997 Jun;40(3):192-8.
319. Liu, P.E. et al. Outcome of tension-free obturator tape procedures in obese and overweight women. Int Urogynecol J 22, 259-63 (2011).
320. Lleberia-Juanos, J. et al. De novo urgency after tension-free vaginal tape versus transobturator tape procedure for stress urinary incontinence. Eur J Obstet Gynecol Reprod Biol 155, 229-32 (2011).
321. Lo, D., Zimmermann, A., Nauta, A., Longaker, M. & Lorenz, H. Scarless fetal skin wound healing update. Birth Defects Res C Embryo Today 96, 237-47 (2012).

322. Lo, T.S. Combined pelvic reconstructive surgery and transobturator tape (monarc) in women with advanced prolapse and urodynamic stress incontinence: a case control series. J Minim Invasive Gynecol 16, 163-8 (2009).
323. Long, C.Y. et al. Lateral excision of tension-free vaginal tape for the treatment of iatrogenic urethral obstruction. Obstet Gynecol 104, 1270-4 (2004).
324. Lord, H.E. et al. A randomized controlled equivalence trial of short-term complications and efficacy of tension-free vaginal tape and suprapubic urethral support sling for treating stress incontinence. BJU Int 98, 367-76 (2006).
325. Madsen, A.M. et al. A cohort study comparing a single-incision sling with a retropubic midurethral sling. Int Urogynecol J 25, 351-8 (2014).
326. Mahajan, S.T., Kenton, K., Bova, D.A. & Brubaker, L. Transobturator tape erosion associated with leg pain. Int Urogynecol J Pelvic Floor Dysfunct 17, 66-8 (2006).
327. Maher, C., Feiner, B., Baessler, K., & Schmid, C. (2013). Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev, 4, CD004014. doi: 10.1002/14651858.CD004014.pub5
328. Mamy, L. et al. Correlation between shrinkage and infection of implanted synthetic meshes using an animal model of mesh infection. Int Urogynecol J 22, 47-52 (2011).
329. Mancini D, Vaillancourt R, Pouliot A, Lin A, Sharp D. Taste and Odour Disturbances in Pediatric Patients Undergoing IV Flush with Normal Saline Administered by Prefilled or Freshly Prepared Syringes: Randomized Single-Blind Study. Can J Hosp Pharm 2014;67:353-7.
330. Manodoro, S. et al. Graft-related complications and biaxial tensiometry following experimental vaginal implantation of flat mesh of variable dimensions. BJOG 120, 244-50 (2013).
331. Marcus-Braun, N. & von Theobald, P. Mesh removal following transvaginal mesh placement: a case series of 104 operations. Int Urogynecol J 21, 423-30 (2010).
332. Marcus-Braun, N., Bourret, A. & von Theobald, P. Persistent pelvic pain following transvaginal mesh surgery: a cause for mesh removal. Eur J Obstet Gynecol Reprod Biol 162, 224-228 (2012).
333. Margulies, R. U., Lewicky-Gaupp, C., Fenner, D. E., McGuire, E. J., Clemens, J. Q., & Delancey, J. O. (2008). Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 199(6), 678 e671-674. doi: 10.1016/j.ajog.2008.07.049
334. Marks, B.K. & Goldman, H.B. Controversies in the management of mesh-based complications: a urology perspective. Urol Clin North Am 39, 419-28 (2012).
335. Maroto, J.R. et al. Transobturator adjustable tape (TOA) permits to correct postoperatively the tension applied in stress incontinence surgery. Int Urogynecol J Pelvic Floor Dysfunct 20, 797-805 (2009).
336. Marques, A.L., Aparicio, C. & Negrao, L. Perineal cellulitis as a late complication of trans-obturator sub-urethral tape, Obtape. Int Urogynecol J Pelvic Floor Dysfunct 18, 821-2 (2007).
337. Celine Mary, Yves Marois, Martin W. King, Gaetan Laroche, Yvan Douville, Louisette Martin, Robert Guidoin, Comparison of the In Vivo Behaviour of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery, *ASAIO Journal*, 44 (1998) 199-206.
338. Masata, J. et al. Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women--2-year follow-up. Int Urogynecol J 23, 1403-12 (2012).
339. Mc Conville, C., Major, I., Friend, D. R., Clark, M. R., Woolfson, A. D., & Malcolm, R. K. (2012). Development of polylactide and polyethylene vinyl acetate blends for the manufacture

of vaginal rings. J Biomed Mater Res B Appl Biomater, 100(4), 891-895. doi: 10.1002/jbm.b.31919

340. McNally, A. & Anderson, J. Interleukin-4 induces foreign body giant cells from human monocytes/macrophages. Differential lymphokine regulation of macrophage fusion leads to morphological variants of multinucleated giant cells. Am J Pathol 147, 1487-99 (1995).

341. Mellier, G., Mistrangelo, E., Gery, L., Philippe, C. & Patrice, M. Tension-free obturator tape (Monarc Subfascial Hammock) in patients with or without associated procedures. Int Urogynecol J Pelvic Floor Dysfunct 18, 165-72 (2007).

342. Mendonca, T.M., Martinho, D. & Dos Reis, J.P. Late urethral erosion of transobturator suburethral mesh (Obtape): a minimally invasive management under local anaesthesia. Int Urogynecol J 22, 37-9 (2011).

343. Meschia, M., Busacca, M., Pifarotti, P. & De Marinis, S. Bowel perforation during insertion of tension-free vaginal tape (TVT). Int Urogynecol J Pelvic Floor Dysfunct 13, 263-5; discussion 265 (2002).

344. Meschia, M., Pifarotti, P., Gattei, U. & Bertozzi, R. Tension-free vaginal tape: analysis of risk factors for failures. Int Urogynecol J Pelvic Floor Dysfunct 18, 419-22 (2007).

345. Mesens, T., Aich, A. & Bhal, P.S. Late erosions of mid-urethral tapes for stress urinary incontinence--need for long-term follow-up? Int Urogynecol J Pelvic Floor Dysfunct 18, 1113-4 (2007).

346. Mesh Distortion Video – Zolnoun

347. Metchnikoff, E. Untersuchungen über die intracellulare Verdauung wirbellosen bei Tieren. Arbeiten aus dem Zoologischen Institut der Universität Wien und der Zoologischen Station in Triest 5, 141-168 (1884).

348. Metz, S. A., Chegini, N., & Masterson, B. J. (1990). In vivo and in vitro degradation of monofilament absorbable sutures, PDS and Maxon. Biomaterials, 11(1), 41-45.

349. Miguel PR, Reusch M, daRosa AL, Carlos JR. JSLS. Laparoscopic hernia repair--complications. 1998 Jan-Mar;2(1):35-40.

350. Milani, R., Salvatore, S., Soligo, M., Pifarotti, P., Meschia, M., & Cortese, M. (2005). Functional and anatomical outcome of anterior and posterior vaginal prolapse repair with prolene mesh. BJOG, 112(1), 107-111. doi: 10.1111/j.1471-0528.2004.00332.x

351. Miller, J., Acar, F., Kaimaktchiev, V., Gultekin, S. & Burchiel, K. Pathology of ilioinguinal neuropathy produced by mesh entrapment: case report and literature review. Hernia 12, 213-6 (2008).

352. Minaglia, S., Ozel, B., Klutke, C., Ballard, C. & Klutke, J. Bladder injury during transobturator sling. Urology 64, 376-7 (2004).

353. Misrai, V. et al. Surgical resection for suburethral sling complications after treatment for stress urinary incontinence. J Urol 181, 2198-202; discussion 2203 (2009).

354. Moalli, P. et al. Tensile properties of five commonly used mid-urethral slings relative to the TVT. Int Urogynecol J Pelvic Floor Dysfunct 19, 655-63 (2008).

355. Mohr, S., Kuhn, P., Mueller, M.D. & Kuhn, A. Painful love-hispareunia after sling erosion of the female partner. J Sex Med 8, 1740-6 (2011).

356. Moss WM. A comparison of open-end versus closed-end vasectomies: a report on 6220 cases. Contraception. 1992 Dec;46(6):521-5.

357. Montoya, T. I., Calver, L., Carrick, K. S., Prats, J., & Corton, M. M. (2011). Anatomic relationships of the pudendal nerve branches. Am J Obstet Gynecol, 205(5), 504 e501-505. doi: 10.1016/j.ajog.2011.07.014

358. Mostafa, A. et al. Multicenter prospective randomized study of single-incision mini-sling vs tension-free vaginal tape-obturator in management of female stress urinary incontinence: a minimum of 1-year follow-up. Urology 82, 552-9 (2013).

359. Mostafa, A., Madhuvrata, P. & Abdel-Fattah, M. Preoperative urodynamic predictors of short-term voiding dysfunction following a transobturator tension-free vaginal tape procedure. Int J Gynaecol Obstet 115, 49-52 (2011).
360. Muhl, T., Binnebosel, M., Klinge, U., & Goedderz, T. (2008). New objective measurement to characterize the porosity of textile implants. J Biomed Mater Res B Appl Biomater, 84(1), 176-183. doi: 10.1002/jbm.b.30859
361. Murphy, M., Holzberg, A., van Raalte, H., Kohli, N., Goldman, H. B., & Lucente, V. (2012). Time to rethink: an evidence-based response from pelvic surgeons to the FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. Int Urogynecol J, 23(1), 5-9. doi: 10.1007/s00192-011-1581-2
362. Murray, S., Haverkorn, R. M., Lotan, Y., & Lemack, G. E. (2011). Mesh kits for anterior vaginal prolapse are not cost effective. Int Urogynecol J, 22(4), 447-452. doi: 10.1007/s00192-010-1291-1
363. Nager, C., Tulikangas, P., Miller, D., Rovner, E. & Goldman, H. Position statement on mesh midurethral slings for stress urinary incontinence. Female Pelvic Med Reconstr Surg 20, 123-5 (2014).
364. Naidu, A. et al. Transobturator tape for stress incontinence: the North Queensland experience. Aust N Z J Obstet Gynaecol 45, 446-9 (2005).
365. Nazemi, T.M. et al. Minimum 24-month followup of the sling for the treatment of stress urinary incontinence. J Urol 179, 596-9 (2008).
366. Neuman, M. Infected hematoma following tension-free vaginal tape implantation. J Urol 168, 2549 (2002).
367. Neuman, M., Sosnovski, V., Goralnik, S., Diker, B. & Bornstein, J. Comparison of two inside-out transobturator suburethral sling techniques for stress incontinence: early postoperative thigh pain and 3-year outcomes. Int J Urol 19, 1103-7 (2012).
368. Nguyen, J. N., & Burchette, R. J. (2008). Outcome after anterior vaginal prolapse repair: a randomized controlled trial. Obstet Gynecol, 111(4), 891-898. doi: 10.1097/AOG.0b013e31816a2489
369. Nicolson, A. & Adeyemo, D. Colovaginal fistula: a rare long-term complication of polypropylene mesh sacrocolpopexy. J Obstet Gynaecol 29, 444-5 (2009).
370. Niemczyk, P., Klutke, J.J., Carlin, B.I. & Klutke, C.G. United States experience with tension-free vaginal tape procedure for urinary stress incontinence: assessment of safety and tolerability. Tech Urol 7, 261-5 (2001).
371. Nieminen, K., Hiltunen, R., Takala, T., Heiskanen, E., Merikari, M., Niemi, K., & Heinonen, P. K. (2010). Outcomes after anterior vaginal wall repair with mesh: a randomized, controlled trial with a 3 year follow-up. Am J Obstet Gynecol, 203(3), 235 e231-238. doi: 10.1016/j.ajog.2010.03.030
372. Nikkolo, C. et al. Three-year results of randomised clinical trial comparing lightweight mesh with heavyweight mesh for inguinal hernioplasty. Hernia 16, 555-9 (2012).
373. Nilsson, C., Palva, K., Aarnio, R., Morcos, E. & Falconer, C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 24, 1265-1269 (2013).
374. Novara, G. et al. Updated systematic review and meta-analysis of the comparative data on colposuspensions, pubovaginal slings, and midurethral tapes in the surgical treatment of female stress urinary incontinence. Eur Urol 58, 218-38 (2010).
375. Novi, J.M. & Mulvihill, B.H. Surgical intervention for stress urinary incontinence: comparison of midurethral sling procedures. J Am Osteopath Assoc 108, 634-8 (2008).
376. Nygaard, I., Brubaker, L., Zyczynski, H. M., Cundiff, G., Richter, H., Gantz, M., . . . Meikle, S. (2013). Long-term outcomes following abdominal sacrocolpopexy for pelvic organ prolapse. JAMA, 309(19), 2016-2024. doi: 10.1001/jama.2013.4919

377. Ogah, J., Cody, D.J. & Rogerson, L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: A short version Cochrane review. Neurourology and Urodynamics 30, 284-291 (2011).
378. Oh, T.H. & Ryu, D.S. Transurethral resection of intravesical mesh after midurethral sling procedures. J Endourol 23, 1333-7 (2009).
379. Olagundoye, V.O., Shah, M.M. & Jackson, S.R. Delayed presentation of small bowel trauma during insertion of tension free vaginal tape (TVT) sling. J Obstet Gynaecol 27, 92-3 (2007).
380. Olah, K.S. Adductor compartment syndrome: An unusual complication of the trans-obturator tape procedure. J Obstet Gynaecol 28, 363-4 (2008).
381. Olsen, A. L., Smith, V. J., Bergstrom, J. O., Colling, J. C., & Clark, A. L. (1997). Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. Obstet Gynecol, 89(4), 501-506. doi: 10.1016/s0029-7844(97)00058-6
382. Olsson, I., Abrahamsson, A.K. & Kroon, U.B. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. Int Urogynecol J 21, 679-83 (2010).
383. Onol, F.F. et al. Minimum 1.5-year results of surgeon-tailored transvaginal mesh repair for female stress urinary incontinence and pelvic organ prolapse. Urology 80, 273-9 (2012).
384. Ordorica, R., Rodriguez, A.R., Coste-Delvecchio, F., Hoffman, M. & Lockhart, J. Disabling complications with slings for managing female stress urinary incontinence. BJU Int 102, 333-6 (2008).
385. Osborn, D.J. et al. Analysis of patient and technical factors associated with midurethral sling mesh exposure and perforation. Int J Urol (2014).
386. Ostergard, D. Degradation, infection and heat effects on polypropylene mesh for pelvic implantation: what was known and when it was known. Int Urogynecol J 22, 771-774 (2011).
387. Ostergard, D. R. (2012). Evidence-based medicine for polypropylene mesh use compared with native tissue vaginal prolapse repair. Urology, 79(1), 12-14. doi: 10.1016/j.urology.2011.07.1438
388. Otto, J. et al. Large-pore PDS mesh compared to small-pore PG mesh. J Invest Surg. 23, 190-6 (2010).
389. Otto, J., Kaldenhoff, E., Kirschner-Hermanns, R., Muhl, T., & Kinge, U. (2013). Elongation of textile pelvic floor implants under load is related to complete loss of effective porosity, thereby favoring incorporation in scar plates. J Biomed Mater Res A. doi: 10.1002/jbm.a.34767
390. Ozel, B., Minaglia, S., Hurtado, E., Klutke, C.G. & Klutke, J.J. Treatment of voiding dysfunction after transobturator tape procedure. Urology 64, 1030 (2004).
391. Pace, G. & Vicentini, C. Female sexual function evaluation of the tension-free vaginal tape (TVT) and transobturator suburethral tape (TOT) incontinence surgery: results of a prospective study. J Sex Med 5, 387-93 (2008).
392. Padmanabhan, P. et al. Approach to management of iatrogenic foreign bodies of the lower urinary tract following reconstructive pelvic surgery. J Urol 187, 1685-90 (2012).
393. Paick, J.S., Oh, S.J., Kim, S.W. & Ku, J.H. Tension-free vaginal tape, suprapubic arc sling, and transobturator tape in the treatment of mixed urinary incontinence in women. Int Urogynecol J Pelvic Floor Dysfunct 19, 123-9 (2008).
394. Palma, P. et al. Transobturator SAFYRE sling is as effective as the transvaginal procedure. Int Urogynecol J Pelvic Floor Dysfunct 16, 487-91 (2005).
395. Palva, K. & Nilsson, C.G. Prevalence of urinary urgency symptoms decreases by mid-urethral sling procedures for treatment of stress incontinence. Int Urogynecol J 22, 1241-7 (2011).
396. Palva, K. et al. A randomized trial comparing tension-free vaginal tape with tension-free vaginal tape-obturator: 36-month results. Int Urogynecol J 21, 1049-55 (2010).

397. Paparella, R. et al. Prospective randomized trial comparing synthetic vs biological out-in transobturator tape: a mean 3-year follow-up study. Int Urogynecol J 21, 1327-36 (2010).
398. Paraiso, M. F., Barber, M. D., Muir, T. W., & Walters, M. D. (2006). Rectocele repair: a randomized trial of three surgical techniques including graft augmentation. Am J Obstet Gynecol, 195(6), 1762-1771. doi: 10.1016/j.ajog.2006.07.026
399. Parekh, M.H., Minassian, V.A. & Poplawsky, D. Bilateral bladder erosion of a transobturator tape mesh. Obstet Gynecol 108, 713-5 (2006).
400. Parnell, B. A., Johnson, E. A., & Zolnoun, D. A. (2012). Genitofemoral and perineal neuralgia after transobturator midurethral sling. Obstetrics & Gynecology, 119(2 Pt 2), 428-431.
401. Patel H, O.D., Sternschuss G. Polypropylene mesh and the host response. Int Urogynecol J 23, 669-79 (2012).
402. Peeters, E. et al. Sperm motility after laparoscopic inguinal hernia repair with lightweight meshes: 3-year follow-up of a randomised clinical trial. Hernia 18, 361-7 (2014).
403. Petri, E. & Ashok, K. Comparison of late complications of retropubic and transobturator slings in stress urinary incontinence. International Urogynecology Journal 23, 321-325 (2012).
404. Petro, C.C. et al. Central failures of lightweight monofilament polyester mesh causing hernia recurrence: a cautionary note. Hernia (2014).
405. Petrou, S.P., Brown, J.A. & Blaivas, J.G. Suprameatal transvaginal urethrolysis. J Urol 161, 1268-71 (1999).
406. Phillips, L., Flood, C.G. & Schulz, J.A. Case report of tension-free vaginal tape-associated bowel obstruction and relationship to body habitus. Int Urogynecol J Pelvic Floor Dysfunct 20, 367-8 (2009).
407. Pierce, L. et al. Long-term histologic response to synthetic and biologic graft materials implanted in the vagina and abdomen of a rabbit model. Am J Obstet Gynecol 200, 546.e1-8 (2009).
408. Pikaart, D.P., Miklos, J.R. & Moore, R.D. Laparoscopic removal of pubovaginal polypropylene tension-free tape slings. JSLS 10, 220-5 (2006).
409. Porena M, Costantini E, Frea B, Giannantoni A, Ranzoni S, Mearini L, Bini V, Kocjancic E Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. Eur Urol.2007 Nov;52(5):1481-90.
410. Poza, J.L. et al. Trans-obturator suburethral tape for female stress incontinence: a cohort of 254 women with 1-year to 2-year follow-up. Acta Obstet Gynecol Scand 87, 232-9 (2008).
411. Price, N., Slack, A., Jwarah, E., & Jackson, S. (2008). The incidence of reoperation for surgically treated pelvic organ prolapse: an 11-year experience. Menopause Int, 14(4), 145-148. doi: 10.1258/mi.2008.008029
412. Public Citizen Petition, August 25, 2011 with supporting statements by Dr. Lewis Wall and Dr. Daniel Elliott.
413. Pushkar, D.Y., Godunov, B.N., Gvozdev, M. & Kasyan, G.R. Complications of mid-urethral slings for treatment of stress urinary incontinence. Int J Gynaecol Obstet 113, 54-7 (2011).
414. Quiroz, L.H. & Cundiff, G.W. Transurethral resection of tension-free vaginal tape under tactile traction. Int Urogynecol J Pelvic Floor Dysfunct 20, 873-5 (2009).
415. Rafii, A., Jacob, D. & Deval, B. Obturator abscess after transobturator tape for stress urinary incontinence. Obstet Gynecol 108, 720-3 (2006).
416. Rajan, B., Polydefkis, M., Hauer, P., Griffin, J. & McArthur, J. Epidermal reinnervation after intracutaneous axotomy in man. J Comp Neurol 457, 24-36 (2003).
417. Rapp, D.E., Govier, F.E. & Kobashi, K.C. Outcomes following mid-urethral sling placement in patients with intrinsic sphincteric deficiency: comparison of Sparc and Monarc slings. Int Braz J Urol 35, 68-75; discussion 75 (2009).

418. Rechberger, T., Futyma, K., Jankiewicz, K., Adamiak, A. & Skorupski, P. The clinical effectiveness of retropubic (IVS-02) and transobturator (IVS-04) midurethral slings: randomized trial. Eur Urol 56, 24-30 (2009).
419. Reich, A., Kohorst, F., Kreienberg, R. & Flock, F. Long-term results of the tension-free vaginal tape procedure in an unselected group: a 7-year follow-up study. Urology 78, 774-7 (2011).
420. Reich, A., Wiesner, K., Kohorst, F., Kreienberg, R. & Flock, F. Comparison of transobturator vaginal tape and retropubic tension-free vaginal tape: clinical outcome and sonographic results of a case-control study. Gynecol Obstet Invest 68, 137-44 (2009).
421. Reinke, J. & Sorg, H. Wound repair and regeneration. Eur Surg Res 49, 35-43 (2012).
422. Rempel DM, Diao E.Entrapment neuropathies: pathophysiology and pathogenesis. J Electromyogr Kinesiol.2004 Feb;14(1):71-5.
423. Reynolds, W.S. et al. Obturator foramen dissection for excision of symptomatic transobturator mesh. J Urol 187, 1680-4 (2012).
424. Richter, H.E. et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med 362, 2066-76 (2010).
425. Ridgeway, B. et al. Early experience with mesh excision for adverse outcomes after transvaginal mesh placement using prolapse kits. Am J Obstet Gynecol 199, 703 e1-7 (2008).
426. Riedler, I. et al. Fournier's gangrene after tension-free vaginal tape (TVT) procedure. Int Urogynecol J Pelvic Floor Dysfunct 15, 145-6 (2004).
427. Robbins and Cotran, Pathologic Basis of Disease, eights edition, 2010, Saunders,
428. Rogo-Gupta, L., & Raz, S. (2013). Pain Complications of Mesh Surgery. In H. B. Goldman (Ed.), Complications of Female Incontinence and Pelvic Reconstructive Surgery (pp. 87-105): Humana Press.
429. Rogo-Gupta, L., Huynh, L., Hartshorn, T.G., Rodriguez, L.V. & Raz, S. Long-term symptom improvement and overall satisfaction after prolapse and incontinence graft removal. Female Pelvic Med Reconstr Surg 19, 352-5 (2013).
430. Roman, H., Marpeau, L., & Hulsey, T. C. (2008). Surgeons' experience and interaction effect in randomized controlled trials regarding new surgical procedures. Am J Obstet Gynecol, 199(2), 108 e101-106. doi: 10.1016/j.ajog.2008.03.002
431. Rosa, D., Angelini, J., Agnelli, J. & Mei, L. The use of optical microscopy to follow the degradation of isotactic polypropylene (iPP) subjected to natural and accelerated aging. Polymer Testing 24, 1022-26 (2005).
432. Rosch R, Junge K, Schachtrupp A, Klinge U, Klosterhalfen B, Schumpelick. Mesh Implants in Hernia Repair. Eur Surg Res 2003; 35: 161-166.
433. Rosenblatt, P., Pulliam, S., Edwards, R. & Boyles, S.H. Suprapubically assisted operative cystoscopy in the management of intravesical TVT synthetic mesh segments. Int Urogynecol J Pelvic Floor Dysfunct 16, 509-11 (2005).
434. Ross, S. et al. Transobturator tape compared with tension-free vaginal tape for stress incontinence: a randomized controlled trial. Obstet Gynecol 114, 1287-94 (2009).
435. Roth, T.M. Management of persistent groin pain after transobturator slings. Int Urogynecol J Pelvic Floor Dysfunct 18, 1371-3 (2007).
436. Roumeguere, T. et al. Trans-obturator vaginal tape (TOT) for female stress incontinence: one year follow-up in 120 patients. Eur Urol 48, 805-9 (2005).
437. Roupret, M. et al. Laparoscopic surgical complete sling resection for tension-free vaginal tape-related complications refractory to first-line conservative management: a single-centre experience. Eur Urol 58, 270-4 (2010).
438. Sabadell, J. et al. Usefulness of retropubic tape for recurrent stress incontinence after transobturator tape failure. Int Urogynecol J 22, 1543-7 (2011).
439. Sahin, A.F., Ilbey, Y.O. & Sahin, N. Vaginocutaneous fistula and inguinal abcess presented 6 years after tension-free vaginal tape sling. Arch Ital Urol Androl 85, 104-6 (2013).

440. Sajid MS, Leaver C, Baig MK, Sains P. Systematic review and meta-analysis ofthe use of lightweight versus heavyweight mesh in open inguinal hernia repair. British J Surg 2012; 99: 29-37.
441. Sakalis, V.I., Gkotsi, A.C., Triantafyllidis, A., Giouris, A. & Charalambous, S. Transurethral holmium laser intravesical tape excision following TVT procedure: results from seven patients in a 12-month follow-up. Int Urogynecol J 23, 769-77 (2012).
442. Salvador M.D., V. Amigó, M.J. Vidal, A. Ribes, L. Contat. Evaluation of chemical degradation of commercial polypropylene, Journal of Materials Processing Technology 143–144 (2003): 693–697
443. Sand, P. K., Koduri, S., Lobel, R. W., Winkler, H. A., Tomezsko, J., Culligan, P. J., & Goldberg, R. (2001). Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol, 184(7), 1357-1362; discussion 1362-1354.
444. Sander, P., Sorensen, F. & Lose, G. Does the tension-free vaginal tape procedure (TVT) affect the voiding function over time? Pressure-flow studies 1 year and 3(1/2) years after TVT. Neurourol Urodyn 26, 995-7 (2007).
445. Scheiner, D.A. et al. Twelve months effect on voiding function of retropubic compared with outside-in and inside-out transobturator midurethral slings. Int Urogynecol J 23, 197-206 (2012).
446. Schierlitz, L. et al. Three-year follow-up of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency. Obstet Gynecol 119, 321-7 (2012).
447. Schimpf, M.O. et al. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. Am J Obstet Gynecol 211, 71 e1-71 e27 (2014).
448. Schmidt, H. et al. Comparison of the Rates of Polypropylene Fibre Degradation Caused by Artificial Light and Sunlight. FIBRES & TEXTILES in Eastern Europe 4, 53-58 (2011).
449. Schwingl PJ, Guess HA. Safety and effectiveness of vasectomy. Fertil Steril. 2000;73(5):923-36.
450. Serati, M. et al. TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. Eur Urol 63, 872-8 (2013).
451. Shah, H.N. & Badlani, G.H. Mesh complications in female pelvic floor reconstructive surgery and their management: A systematic review. Indian J Urol 28, 129-53 (2012).
452. Shah, K., Nikolavsky, D., Gilsdorf, D. & Flynn, B.J. Surgical management of lower urinary mesh perforation after mid-urethral polypropylene mesh sling: mesh excision, urinary tract reconstruction and concomitant pubovaginal sling with autologous rectus fascia. Int Urogynecol J 24, 2111-7 (2013).
453. Shaker, H.S., Ban, H.M., Hegazy, A.S. & Mansour, M.F. Functional and quality of life outcome of transobturator tape for treatment of female stress urinary. Int Urogynecol J 22, 99-103 (2011).
454. Shepherd JP, Feola AJ, Abramowitch SD, Moalli PAUniaxial biomechanical properties of seven different vaginally implanted meshes for pelvic organ prolapse. Int Urogynecol J. 2012 May;23(5):613-20.
455. Siddighi, S. & Karram, M.M. Surgical and nonsurgical approaches to treat voiding dysfunction following antiincontinence surgery. Curr Opin Obstet Gynecol 19, 490-5 (2007).
456. Siddiqui, K., Raj, H., Flynn, R.J., Grainger, R. & Thornhill, J.A. Minimally invasive treatment of female stress urinary incontinence: 100 cases using SPARC sling. Ir J Med Sci 177, 39-42 (2008).
457. Siegel, A.L. Vaginal mesh extrusion associated with use of Mentor transobturator sling. Urology 66, 995-9 (2005).
458. Siegel, A.L., Kim, M., Goldstein, M., Levey, S. & Ilbeigi, P. High incidence of vaginal mesh extrusion using the intravaginal slingplasty sling. J Urol 174, 1308-11 (2005).

459. Silva-Filho, A.L., Candido, E.B., Noronha, A. & Triginelli, S.A. Comparative study of autologous pubovaginal sling and synthetic transobturator (TOT) SAFYRE sling in the treatment of stress urinary incontinence. Arch Gynecol Obstet 273, 288-92 (2006).
460. Sivanesan, K., Abdel-Fattah, M. & Tierney, J. Perineal cellulitis and persistent vaginal erosion after transobturator tape (Obtape)--case report and review of the literature. Int Urogynecol J Pelvic Floor Dysfunct 18, 219-21 (2007).
461. Sivaslioglu, A.A., Unlubilgin, E. & Dolen, I. The multifilament polypropylene tape erosion trouble: tape structure vs surgical technique. Which one is the cause? Int Urogynecol J Pelvic Floor Dysfunct 19, 417-20 (2008).
462. Sivaslioglu, A.A., Unlubilgin, E., Aydogmus, S., Keskin, L. & Dolen, I. A prospective randomized controlled trial of the transobturator tape and tissue fixation mini-sling in patients with stress urinary incontinence: 5-year results. J Urol 188, 194-9 (2012).
463. Skala, C. et al. The IUGA/ICS classification of complications of prosthesis and graft insertion: a comparative experience in incontinence and prolapse surgery. Int Urogynecol J 22, 1429-35 (2011).
464. Smith, T. et al. Pathologic evaluation of explanted vaginal mesh: interdisciplinary experience from a referral center. Female Pelvic Med Reconstr Surg 19, 238-41 (2013).
465. Stanford, E. & Paraiso, M. A Comprehensive Review of Suburethral Sling Procedure Complications. J Minim Invasive Gynecol 15, 132-145 (2008).
466. Stanford, E. J., Cassidenti, A., & Moen, M. D. (2012). Traditional native tissue versus mesh-augmented pelvic organ prolapse repairs: providing an accurate interpretation of current literature. Int Urogynecol J, 23(1), 19-28. doi: 10.1007/s00192-011-1584-z
467. Sternschuss, G. (2012). Re: Post-Implantation Alterations of Polypropylene in the Human. J Urol. doi: 10.1016/j.juro.2012.11.164
468. Sternschuss, G., Ostergard, D. & Patel, H. Post-Implantation Alterations of Polypropylene in the Human. J Urol 188, 27-32 (2012).
469. Sternschuss, G., Ostergard, D. R., & Patel, H. (2012). Erratum: Post-implantation alterations of polypropylene in the human. J Urol, 188(1), 27-32. doi: 10.1016/j.juro.2012.02.2559
470. Stewart MJ, "On the use of polarized light in the detection and investigation of suture materials embedded in the tissues," The British Medical Journal, pp. 663-5, May 15, 1920
471. Strasberg, S.M., Linehan, D.C. & Hawkins, W.G. The accordion severity grading system of surgical complications. Ann Surg 250, 177-86 (2009).
472. Su, T.H. et al. Tension-free vaginal tape-obturator procedure for treatment of severe urodynamic stress incontinence: subjective and objective outcomes during 2 years of follow-up. J Obstet Gynaecol Res 35, 1077-82 (2009).
473. Sun, M.J. & Tsai, H.D. Is transobturator suburethral sling effective for treating female urodynamic stress incontinence with low maximal urethral closure pressure? Taiwan J Obstet Gynecol 50, 20-4 (2011).
474. Sung, V. W., Rogers, R. G., Schaffer, J. I., Balk, E. M., Uhlig, K., Lau, J., . . . Young, S. B. (2008). Graft use in transvaginal pelvic organ prolapse repair: a systematic review. Obstet Gynecol, 112(5), 1131-1142. doi: 10.1097/AOG.0b013e3181898ba9
475. Sung, V.W., Kassis, N. & Raker, C.A. Improvements in physical activity and functioning after undergoing midurethral sling procedure for urinary incontinence. Obstet Gynecol 120, 573-80 (2012).
476. Suskind, A.M. et al. Effectiveness of mesh compared with nonmesh sling surgery in Medicare beneficiaries. Obstet Gynecol 122, 546-52 (2013).
477. Svabík, K. et al. Ultrasound appearances after mesh implantation--evidence of mesh contraction or folding? Int Urogynecol J 22, 529-33 (2011).

478. Svenningsen, R., Staff, A.C., Schiotz, H.A., Western, K. & Kulseng-Hanssen, S. Long-term follow-up of the retropubic tension-free vaginal tape procedure. Int Urogynecol J 24, 1271-8 (2013).
479. Sweat, S.D. et al. Polypropylene mesh tape for stress urinary incontinence: complications of urethral erosion and outlet obstruction. J Urol 168, 144-6 (2002).
480. Sweeney, D.D. & Leng, W.W. Treatment of postoperative voiding dysfunction following incontinence surgery. Curr Urol Rep 6, 365-70 (2005).
481. Swift, S., Woodman, P., O'Boyle, A., Kahn, M., Valley, M., Bland, D., . . . Schaffer, J. (2005). Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. Am J Obstet Gynecol, 192(3), 795-806. doi: 10.1016/j.ajog.2004.10.602
482. Takahashi, S. et al. Transvaginal mesh (TVM) reconstruction with TVT/TOT sling for vaginal prolapse concurrent with stress urinary incontinence. Aktuelle Urol 41 Suppl 1, S20-3 (2010).
483. Tang, L. & Eaton, J. Fibrin(ogen) mediates acute inflammatory responses to biomaterials. J Exp Med 178, 2147-56 (1993).
484. Tang, L. & Eaton, J. Natural responses to unnatural materials: A molecular mechanism for foreign body reactions. Mol Med 5, 351-8 (1999).
485. Tanuri, A.L. et al. [Retropubic and transobturator sling in treatment of stress urinary incontinence]. Rev Assoc Med Bras 56, 348-54 (2010).
486. Taylor, C., Siddiqi, I. & Brody, G. Anaplastic large cell lymphoma occurring in association with breast implants: review of pathologic and immunohistochemical features in 103 cases. Appl Immunohistochem Mol Morphol 21, 13-20 (2013).
487. Tcherniakovsky, M., Fernandes, C.E., Bezerra, C.A., Del Roy, C.A. & Wroclawski, E.R. Comparative results of two techniques to treat stress urinary incontinence: synthetic transobturator and aponeurotic slings. Int Urogynecol J Pelvic Floor Dysfunct 20, 961-6 (2009).
488. The Federal and Drug Administration. FDA Safety Communication: UPDATE on Serious Complications Associated with transvaginal placement of surgical mesh for pelvic organ prolapse (2011)
489. Thompson, P. & Prince, H. Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis. Curr Hematol Malig Rep 8, 196-210 (2013).
490. Thompson, P. & Prince, H. Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis. Curr Hematol Malig Rep 8, 196-210 (2013).
491. Tijdink, M.M., Vierhout, M.E., Heesakkers, J.P. & Withagen, M.I. Surgical management of mesh-related complications after prior pelvic floor reconstructive surgery with mesh. Int Urogynecol J 22, 1395-404 (2011).
492. Tikkinen, K.A. & Auvinen, A. Does the imprecise definition of overactive bladder serve commercial rather than patient interests? Eur Urol 61, 746-8; discussion 749-50 (2012).
493. Tinelli, A. et al. Presurgical promestriene therapy in postmenopausal women with stress urinary incontinence. Gynecol Endocrinol 23, 445-50 (2007).
494. Tommaselli, G.A. et al. Efficacy and safety of TVT-O and TVT-Secur in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 21, 1211-7 (2010).
495. Tommaselli, G.A. et al. Tension-free vaginal tape-O and -Secur for the treatment of stress urinary incontinence: a thirty-six-month follow-up single-blind, double-arm, randomized study. J Minim Invasive Gynecol 20, 198-204 (2013).
496. Trabuco, E.C. et al. Medium-term comparison of continence rates after rectus fascia or midurethral sling placement. Am J Obstet Gynecol 200, 300 e1-6 (2009).

497. TROYIMOVA N. F., V. V. Z1NOV'YEV and V. V. •HARITONOV, KINETIC REGULARITIES OF THE OXIDATIVE DEGRADATION OF SOLID POLYPROPYLENE, Polymer Science U.S.S.R. Vol. 23, No. 5, pp. 1239-1247, 1981
498. Tseng, L.H., Wang, A.C., Lin, Y.H., Li, S.J. & Ko, Y.J. Randomized comparison of the suprapubic arc sling procedure vs tension-free vaginal taping for stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 16, 230-5 (2005).
499. Ugurlucan, F.G., Erkan, H.A., Onal, M. & Yalcin, O. Randomized trial of graft materials in transobturator tape operation: biological versus synthetic. Int Urogynecol J 24, 1315-23 (2013).
500. Ulmsten, U. & Petros, P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 29, 75-82 (1995).
501. Urinary Incontinence Treatment, N. The Trial of Mid-Urethral Slings (TOMUS): Design and Methodology. J Appl Res 8 (2008).
502. Usher, F., Cogan, J. & Lowry, T. A new technique for the repair of inguinal and incisional hernias. Arch Surg 81, 847 (1960).
503. Uzzaman, M.M., Ratnasingham, K. & Ashraf, N. Meta-analysis of randomized controlled trials comparing lightweight and heavyweight mesh for Lichtenstein inguinal hernia repair. Hernia 16, 505-18 (2012).
504. Vaginal Placement of Synthetic Mesh for Pelvic Organ Prolapse. ACOG Committee Opinion No. 513. American College of Obstetricians and Gynecologists. Obstet Gynecol 2011; 118(6): 1459-1464.
505. Van Baelen, A.A. & Delaere, K.P. Repeat transobturator tape after failed mid-urethral sling procedure: follow-up with questionnaire-based assessment. Urol Int 83, 399-403 (2009).
506. Van Geelen, J. & Dwyer, P. Where to for pelvic organ prolapse treatment after the FDA pronouncements? A systematic review of the recent literature. Int Urogynecol J 24, 707-18 (2013).
507. Vascellari, M., Melchiotti, E. & Mutinelli, F. Fibrosarcoma with Typical Features of Postinjection Sarcoma at Site of Microchip Implant in a Dog: Histologic and Immunohistochemical Study. Veterinary Pathology Online 43, 545-548 (2006).
508. Verbrugghe, A., De Ridder, D. & Van der Aa, F. A repeat mid-urethral sling as valuable treatment for persistent or recurrent stress urinary incontinence. Int Urogynecol J 24, 999-1004 (2013).
509. Vervest, H., Bongers, M. & van der Wurff, A. Nerve injury: an exceptional cause of pain after TVT. Int Urogynecol J Pelvic Floor Dysfunct. 2006 Nov;17(6):665-7 17, 665-7 (2006).
510. Vollebregt, A., Fischer, K., Gietelink, D., & van der Vaart, C. H. (2011). Primary surgical repair of anterior vaginal prolapse: a randomised trial comparing anatomical and functional outcome between anterior colporrhaphy and trocar-guided transobturator anterior mesh. BJOG, 118(12), 1518-1527. doi: 10.1111/j.1471-0528.2011.03082.x
511. Vollebregt, A., Troelstra, A., & van der Vaart, C. H. (2009). Bacterial colonisation of collagen-coated polypropylene vaginal mesh: are additional intraoperative sterility procedures useful? Int Urogynecol J Pelvic Floor Dysfunct, 20(11), 1345-1351. doi: 10.1007/s00192-009-0951-5
512. Wadie, B.S. & El-Hefnawy, A.S. TVT versus TOT, 2-year prospective randomized study. World J Urol 31, 645-9 (2013).
513. Wadie, B.S., Edwan, A. & Nabeeh, A.M. Autologous fascial sling vs polypropylene tape at short-term followup: a prospective randomized study. J Urol 174, 990-3 (2005).
514. Wadie, B.S., Mansour, A., El-Hefnawy, A.S., Nabeeh, A. & Khair, A.A. Minimum 2-year follow-up of mid-urethral slings, effect on quality of life, incontinence impact and sexual function. Int Urogynecol J 21, 1485-90 (2010).
515. Wall, L. L., & Brown, D. (2010). The perils of commercially driven surgical innovation. Am J Obstet Gynecol, 202(1), 30 e31-34. doi: 10.1016/j.ajog.2009.05.031

516. Waltregny, D. et al. TVT-O for the treatment of female stress urinary incontinence: results of a prospective study after a 3-year minimum follow-up. Eur Urol 53, 401-8 (2008).
517. Wang, A., Lee, L., Lin, C. & Chen, J. A histologic and immunohistochemical analysis of defective vaginal healing after continence taping procedures: a prospective case-controlled pilot study. Am J Obstet Gynecol 191, 1868-74 (2004).
518. Wang, Y.J. et al. Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT-Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 22, 1369-74 (2011).
519. Ward, K.L., Hilton, P., Uk & Ireland, T.V.T.T.G. Tension-free vaginal tape versus colposuspension for primary urodynamic stress incontinence: 5-year follow up. BJOG 115, 226-33 (2008).
520. Washington, J. L. (2011). Commercial products for pelvic repair. Female Pelvic Med Reconstr Surg, 17(5), 218-225. doi: 10.1097/SPV.0b013e31822d407a
521. Weber, A. M., Walters, M. D., Piedmonte, M. R., & Ballard, L. A. (2001). Anterior colporrhaphy: a randomized trial of three surgical techniques. Am J Obstet Gynecol, 185(6), 1299-1304; discussion 1304-1296. doi: 10.1067/mob.2001.119081
522. Weinberger, J.M., Purohit, R.S. & Blaivas, J.G. Mesh infection of a male sling. J Urol 190, 1054-5 (2013).
523. Welty G, Klinge U, Klosterhalfen B, Kasperk R, Schumpelick V. Functional impairment and complaints following incisional hernia repair with different polypropylene meshes. Hernia 2001; 5: 142-147.
524. Wijffels, S.A., Elzevier, H.W. & Lycklama a Nijeholt, A.A. Transurethral mesh resection after urethral erosion of tension-free vaginal tape: report of three cases and review of literature. Int Urogynecol J Pelvic Floor Dysfunct 20, 261-3 (2009).
525. Wilty, G., Klinge, U., Klosterhalfen, B., Kasperk, R. & Schumpelick, V. Functional impairment and complaints following incisional hernia repair with different polypropylene meshes. Hernia 5, 142-7 (2001).
526. Withagen, M. I., Milani, A. L., den Boon, J., Vervest, H. A., & Vierhout, M. E. (2011). Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol, 117(2 Pt 1), 242-250. doi: 10.1097/AOG.0b013e318203e6a5
527. Withagen, M.I. & Milani, A.L. Which factors influenced the result of a tension free vaginal tape operation in a single teaching hospital? Acta Obstet Gynecol Scand 86, 1136-9 (2007).
528. Witherspoon, P., Bryson, G., Wright, D., Reid, R. & O'Dwyer, P. Carcinogenic potential of commonly used hernia repair prostheses in an experimental model. Br J Surg 91, 368-72 (2004).
529. Wood, A. et al. Materials characterization and histological analysis of explanted polypropylene, PTFE, and PET hernia meshes from an individual patient. J Mater Sci Mater Med 24, 1113-22 (2013).
530. Wu, J.Y., He, H.C., Chen, S.W., Jin, X.D. & Zhou, Y.X. Surgical therapies of female stress urinary incontinence: experience in 228 cases. Int Urogynecol J 21, 645-9 (2010).
531. Yah, H., et al. SEM Study of Alteration of Meshes Explanted. .IUGA 2007 – Cancun Morphologic Correlation of Functional Abdominal Wall Mechanics After Mesh
532. Yamada, B., Govier, F., Stefanovic, K. & Kobashi, K. High rate of vaginal erosions associated with the mentor ObTape. J Urol 176, 651-4 (2006).
533. Yamada, B.S., Govier, F.E., Stefanovic, K.B. & Kobashi, K.C. Vesicovaginal fistula and mesh erosion after Perigee (transobturator polypropylene mesh anterior repair). Urology 68, 1121 e5-7 (2006).

534. Yang, C.H. et al. A retrospective study comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of female stress urinary incontinence --- a preliminary report. J Chin Med Assoc 70, 541-4 (2007).
535. Yang, X. et al. TVT-O vs. TVT for the treatment of SUI: a non-inferiority study. Int Urogynecol J 23, 99-104 (2012).
536. Yazdankhah Kenary, A. et al. Randomized clinical trial comparing lightweight mesh with heavyweight mesh for primary inguinal hernia repair. Hernia 17, 471-7 (2013).
537. Yeung, P., Jr., Sokol, A., Walton, B. & Iglesia, C. Thigh abscess mistaken for sarcoma following transobturator tape: a case report and literature review. J Minim Invasive Gynecol 14, 657-9 (2007).
538. Yoon, C.J. & Jung, H.C. Three-year outcomes of the innovative replacement of incontinence surgery procedure for treatment of female stress urinary incontinence: comparison with tension-free vaginal tape procedure. J Korean Med Sci 22, 497-501 (2007).
539. Youn, C.S., Shin, J.H. & Na, Y.G. Comparison of TOA and TOT for Treating Female Stress Urinary Incontinence: Short-Term Outcomes. Korean J Urol 51, 544-9 (2010).
540. Young, N.S., Ioannidis, J.P. & Al-Ubaydli, O. Why current publication practices may distort science. PLoS Med 5, e201 (2008).
541. Young, S.B., Howard, A.E. & Baker, S.P. Mersilene mesh sling: short- and long-term clinical and urodynamic outcomes. Am J Obstet Gynecol 185, 32-40 (2001).
542. Zoorob, D. & Karram, M. Management of mesh complications and vaginal constriction: a urogynecology perspective. Urol Clin North Am 39, 413-8 (2012).
543. Zugor, V. et al. TVT vs. TOT: a comparison in terms of continence results, complications and quality of life after a median follow-up of 48 months. Int Urol Nephrol 42, 915-20 (2010).
544. 2010 TVT-O IFU
545. Klinge, U., Otto, J., Mühl, T. *High Structural Stability of Textile Implants Prevents Pore Collapse and Preserves Effective Porosity at Strain.* Biomed Research International. Voume 2015, Artice ID 953209
546. Barone, W., Amini, R., Maiti, S., Moalli, P., Abramowitch, S. *The Impact of boundary conditions on surface curvature of polypropylene mesh in response to uniaxial loading.* Journal of Biomechanics (2015). http://dx.doi.org/10.1016/j.jbiomech.2015.02.061
547. Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polyropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7
548. Cobb WS, Burns JM, Peindl RD, Carbonell AM, Matthews BD, Kercher KW, Heniford BT Textile analysis of heavyweight, mid-weight, and lightweight polypropylene mesh in a porcine ventral hernia model..J Surg Res. 2006 Nov;136(1):1-7. Epub 2006 Sep 22.
549. Tunn R, Picot A, Marschke J, Gauruder-Burmester A, Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele. Ultrasound Obstet Gynecol. 2007 Apr;29(4):449-52
550. Velemir L, Amblard J, Fatton B, Savary D, Jacquetin B, Transvaginal mesh repair of anterior and posterior vaginal wall prolapse: a clinical and ultrasonographic study. Ultrasound Obstet Gynecol (2010)
551. Letouzey V, Fritel X, Pierre F, Courtieu C, Marès P, de Tayrac R. Informing a patient about surgical treatment for pelvic organ prolapse. Gynecol Obstet Fertil. 2010 Apr;38(4):255-60.
552. Rogowski, A., Bienkowski, P., Tosiak, A., Jerzak, M., Mierzejewski, P., Baranowsi, W. *mesh retraction correlates with vaginal pain and overactive bladder symptoms after anterior vaginal mesh repair.* Int Urogynecol J (2013) 24:2087–2092
553. Mazza, E., Ehret, A. *Mechanical biocompatibility of highly deformable biomedical materials.* Journal of the Mechanical Behavior of Biomedical Materials. Int Urogynecol J (2013) 24:2087–2092
554. "Mesh shrinkage: How prevent, how to manage?" PowerPoint presentation by L. Velemir, B. Fatton and B. Jacquetin.

555. http://www.hmcpolymers.com/uploads/files/resources/hmc-pp-chemical-resistance.PDF
http://www.gilsoneng.com/reference/ChemRes.pdf
https://plasticpipe.org/pdf/tr-19_thermoplastic_pipe_for_transport_of_chemical.pdf
http://www.quickcutgasket.com/pdf/Chemical-Resistance-Chart.pdf
http://www.reln.com.au/site/DefaultSite/filesystem/documents/PP_Chemical_Resistance.pdf
556. V. V. Iakovlev, S. A. Guelcher, R. Bendavid. In vivo degradation of polypropylene: microscopic analysis of meshes explanted from patients. Journal of Biomedical Materials Research part B: Applied Biomaterials 2015; in press
557. J. G. Blaivas, R. S. Purohit, M. S. Benedon, G. Mekel, M. Stern, M. Billah, K. Olugbade, R. Bendavid, V. Iakovlev. Safety considerations for synthetic sling surgery. Nature Reviews Urology 2015; in press.
558. de Tayrac R, Letouzey V. Basic science and clinical aspects of mesh infection in pelvic floor reconstructive surgery. Int Urogynecol J 2011;22:775–780.
559. European Hernia Symposium Announcement - Berlin, September, 2015
560. Dietz, et al.; Mesh Contraction: myth or reality. Am J Obstet Gynecol 2011;204:173.e1-4
561. Lico, et al.; Estimation of Polypropylene Degradation during Recycling Process by Using Vibration Spectroscopy Methods. (2014) ICRAE
562. ETH.MESH.159554738 – Prolene (Polypropylene) Microcracks 1983
563. ETH.MESH.15955440 – Human retrieval Speciments From Dr. Roger Gregory, Norfolk Surgical Group
564. ETH.MESH.15955462 – Examination of Prolene (Polypropylene) Suture from Human Cardiovascular Explants
565. Miao, L., et al. (2015) Physical Characteristics of Medical Textile Prostheses Design for Hernia Repair: A Comprehensive Analysis of Select Commercial Devices. Materials. 8148-8168
566. Certificate of Accreditation – St. Michael's Hospital, Toronto
567. Jefferson, D. N. (1981). Renaut Body Distribution at Sites of Human Peripheral Nerve Entrapment. Journal of Neurological Sciences, 49:19-29.
568. Ortman, J. S. (1983). The Experimental Production of Renaut Bodies. Journal of Neurological Sicences, 62:233-241.
569. In J. Bilbau, Biopsy Diagnosis of Peripheral Neuropathy (p. 477). Springer.
570. Pina-Oviedo, S. D.-H.-H. (2009). Immunohistochemical characterization of Renaut bodies in superficial digital nerves: further evidence supporting their perineurial cell origin. Journal of the Peripheral Nervous System, 14:22-26.
571. Li, J., et al; Deterioration of Polypropylene/Silcone Dioxide Nanocomposites Before Oxidative Degradation. Journal of Applie Polymer Science, Vol. 113, 601-606 (2009)
572. Cermak, R., et al; Photodegradation of Polypropylene with sobitol-based nucleating agent. Latest Trends on Engineering Mechanics, structures, engineering geology.
573. Rolando, Richard; The effects of radiation on polypropylene. (1991) Tappi Journal
574. Occhino JA, Casiano ER, Trabuco EC, Klingele CJ. A three-incision approach to treat persistent vaginal exposure and sinus tract formation related to ObTape mesh insertion. Int Urogynecol J. 2012 Sep;23(9):1307-9.

575. Lowery WJ, Dooley Y, Kost E. Small-pore polypropylene slings: still out there. Int Urogynecol J. 2010 Jan;21(1):125-7.
576. Bazi T. Re: High rate of vaginal erosions associated with the mentor ObTape. J Urol. 2007 Feb;177(2):795.
577. Onyeka BA, Ogah J. Vaginal tape erosion following transobturator tape (TOT) operation for stress urinary incontinence. J Obstet Gynaecol. 2006 Nov;26(8):802-3.
578. Abdel-Fattah M, Sivanesan K, Ramsay I, Pringle S, Bjornsson S. How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. BJU Int. 2006 Sep;98(3):594-8.
579. Yamada BS, Govier FE, Stefanovic KB, Kobashi KC. High rate of vaginal erosions associated with the mentor ObTape. J Urol. 2006 Aug;176(2):651-4.
580. Deval B, Ferchaux J, Berry R, Gambino S, Ciofu C, Rafii A, Haab F.Objective and subjective cure rates after trans-obturator tape (OBTAPE) treatment of female urinary incontinence. Eur Urol. 2006 Feb;49(2):373-7.
581. Siegel AL. Vaginal mesh extrusion associated with use of Mentor transobturator sling. Urology. 2005 Nov;66(5):995-9
582. Karp D1, Apostolis C, Lefevre R, Davila GW. Atypical graft infection presenting as a remote draining sinus. Obstet Gynecol. 2009 Aug;114(2 Pt 2):443-5.
583. Baessler K1, Hewson AD, Tunn R, Schuessler B, Maher CF. Severe mesh complications following intravaginal slingplasty. Obstet Gynecol. 2005 Oct;106(4):713-6.
584. Bafghi A1, Benizri EI, Trastour C, Benizri EJ, Michiels JF, Bongain A. Multifilament polypropylene mesh for urinary incontinence: 10 cases of infections requiring removal of the sling. BJOG. 2005 Mar;112(3):376-8.
585. Klinge U1, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V. Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. J Biomed Mater Res. 2002;63(6):765-71.
586. Engelsman AF1, van Dam GM, van der Mei HC, Busscher HJ, Ploeg RJ. In vivo evaluation of bacterial infection involving morphologically different surgical meshes. Ann Surg. 2010 Jan;251(1):133-7.
587. Engelsman AF1, van der Mei HC, Busscher HJ, Ploeg RJ. Morphological aspects of surgical meshes as a risk factor for bacterial colonization. Br J Surg. 2008 Aug;95(8):1051-9.
588. Bendavid R, Lou W, Grischkan D, Koch A, Petersen K, Morrison J, Iakovlev V. A mechanism of mesh-related post-herniorrhaphy neuralgia. Hernia. 2015 Nov 23. [Epub ahead of print]
589. Stav K, Dwyer PL.Urinary bladder stones in women. Obstet Gynecol Surv. 2012 Nov;67(11):715-25.
590. Simsek A, Ozgor F, Akbulut MF, Sönmezay E, Yuksel B, Sarılar O, Berberoglu AY, Gurbuz ZG. Management of bladder stones associated with foreign bodies following incontinence and contraception surgery. Arch Ital Urol Androl. 2014 Jun 30;86(2):108-11.
591. Su YR, Chan PH. Mesh migration into urinary bladder after open ventral herniorrhaphy with mesh: a case report. Int Surg. 2014 Jul-Aug;99(4):410-3.
592. Chin K, Ripperda CM, Schaffer JI, Wai CY. Cystolith formation complicating single-incision sling. Female Pelvic Med Reconstr Surg. 2014 May-Jun;20(3):177-9.

593. Yoshizawa T, Yamaguchi K, Obinata D, Sato K, Mochida J, Takahashi S. Laparoscopic transvesical removal of erosive mesh after transobturator tape procedure. Int J Urol. 2011 Dec;18(12):861-3.
594. Feiner B, Auslender R, Mecz Y, Lissak A, Stein A, Abramov Y. Removal of an eroded transobturator tape from the bladder using laser cystolithotripsy and cystoscopic resection. Urology. 2009 Mar;73(3):681.e15-6.
595. Nygaard IE, McCreery R, Brubaker L, Connolly A, Cundiff G, Weber AM, Zyczynski H; Pelvic Floor Disorders Network. Abdominal sacrocolpopexy: a comprehensive review. Obstet Gynecol. 2004;104(4):805-23.
596. Barnes MG. Irritable bowel syndrome: a "mesh" of a situation. J Am Board Fam Med. 2012;25(1):120-3.
597. Chen MJ, Tian YF. Intraperitoneal migration of a mesh plug with a small intestinal perforation: report of a case. Surg Today. 2010;40(6):566-8.
598. Lo DJ1, Bilimoria KY, Pugh CM. Bowel complications after prolene hernia system (PHS) repair: a case report and review of the literature. Hernia. 2008;12(4):437-40.
599. Ojo P1, Abenthroth A, Fiedler P, Yavorek G. Migrating mesh mimicking colonic malignancy. Am Surg. 2006;72(12):1210-1.
600. Ferrone R, Scarone PC, Natalini G. Late complication of open inguinal hernia repair: small bowel obstruction caused by intraperitoneal mesh migration. Hernia. 2003;7(3):161-2.
601. Chuback JA, Singh RS, Sills C, Dick LS. Small bowel obstruction resulting from mesh plug migration after open inguinal hernia repair. Surgery. 2000;127(4):475-6.

Exhibit A

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Professional qualifications

- 2006 — American Board of Pathology, Anatomical Pathology
- 2006 — Royal College of Physicians and Surgeons of Canada, Anatomical Pathology
- 2002 — United States Medical Licensing Exams (USMLE 1-3)
- 2000 — Medical Council of Canada (LMCC)
- 2000 — Educational Commission for Foreign Medical Graduates (ECFMG)
- 1994 — Medical Doctor, Tyumen State Medical Institute, Russia

Medical Licensure

- 2007-current — Independent practice, Ontario, Canada (CPSO)
- 2006-current — Full unrestricted license, State of Michigan, USA

Academic appointments

- 2008 — Assistant Professor, Department of Laboratory Medicine and Pathobiology, University of Toronto
- 2007 — Lecturer, Department of Laboratory Medicine and Pathobiology, University of Toronto

Awards and grants

- 2008 — Dean's Fund award , Faculty of Medicine, University of Toronto, total $10,000 for 5 years
- 1986-1992 — Stipend for high academic results, Tyumen Medical academy, 6 times during the course of studies

Professional membership

- 2007-current — Member, Canadian Association of Pathologists
- 2006-current — Fellow, Royal College of Physicians and Surgeons of Canada (FRCPC)
- 2006-current — Fellow, College of American Pathologists (FCAP)
- 2002-current — Member, United States and Canadian Academy of Pathology
- 2001-current — Canadian Medical Protective Association

EDUCATION

Fellowship

- 2005 – 2007
  - Canadian Institute for Health Research (CIHR) Molecular Oncological Pathology program; Ontario Cancer Institute/Princess Margaret Hospital, Toronto, Canada

-Training program for translational oncologic pathology, projects at two labs:

1. Dr. Susan Done, clinician-scientist, breast pathologist
Focus: data analysis of array Comparative Genomic Hybridization, validation by immunohistochemistry, image and data analysis.

2. Dr. David Hedley, clinician-scientist, medical oncologist
Focus: image and data analysis of immunohistochemistry, assessment of sampling error due to intratumoral heterogeneity.

Residency

- 2001 – 2006
  - Anatomic Pathology, University of Manitoba, Winnipeg, Manitoba, Canada. Royal College of Physicians of Canada and American Board of Pathology accredited program
  - Elective: Orthopaedic pathology (2 months), Mount Sinai Hospital, University of Toronto, Toronto, Canada.

Observership

- 2000-2001
  - Pathology department, Sunnybrook and Women's College Health Sciences Centre, Toronto, Canada.

Medical education

- 1986-1994
  - Tyumen State Medical Institute (Academy), Tyumen, Russia.

Medical Doctor degree (extended by two years due to mandatory military service).

Projects/interests:
- part time employment for anatomical dissections
- student project "WBC differential changes during menstrual cycle"
- internship research project "Fusion of bone tissues with porous and shape memory titanium alloys".

WORK EXPERIENCE

- 2012- current
  - Director of Cytopathology, Division of Pathology, St. Michael's Hospital, Toronto, Canada

  - GYN and medical cytology, liquid based. 18,000 annual case load for the department; 3 full time and 1 part-time cytotechnologists; medical cytology includes EBUS FNA of the pancreato-biliary tree and endobronchial sampling of lymph nodes with on-site assessment.

- 2007-current
  - Anatomic Pathologist, Division of Pathology, St. Michael's Hospital, Toronto, Canada

  - Anatomic pathology and cytology at a tertiary teaching hospital. oncologic GI, breast, GU, endocrine services and a mix of other areas
  - Intraoperative consultations with occasional coverage of neuropathology
  - Interests in non-neoplastic bone, head/neck and endocrine pathology
  - Tumor rounds for ENT/endocrine group

- 1994-1997
  - Physician, Tyumen Rehabilitation Center, Tyumen, Russia

  -Amputee and musculo-skeletal outpatient clinic.

ADMINISTRATIVE EXPERIENCE

- 2012-current
  - Director of Cytopathology, Division of Pathology, St. Michael's Hospital

- 2010-current
  - Member, Committee for Undergraduate Medical Education of the Department of Laboratory medicine and Pathobiology, Faculty of Medicine, University of Toronto, Toronto, Canada

- 2008-2013
  - Pathologist scheduling, Division of Pathology, St. Michael's Hospital, Toronto, Canada

- 2010-2013
  - Chair, Quality of Care committee, Department of Laboratory Medicine, St. Michael's Hospital, Toronto, Canada

- 2003 – 2005
  - Chief resident, Anatomical Pathology program, University of Manitoba, Winnipeg, Canada

- 2004-2005
  - Trainee member, Promotion committee, Pathology department, University of Manitoba, Winnipeg, Canada

- 2002-2004
  - Board member, PARIM (Professional Association of Residents and Interns of Manitoba), Winnipeg, Canada

- 1986-1987
  - Medical student representative, Medical professional union, Tyumen Medical Institute, Tyumen, Russia

TEACHING EXPERIENCE

- 2008-present
  - Undergraduate Medical Education and Department of Laboratory medicine and Pathobiology, Faculty of Medicine, University of Toronto, Toronto, Canada

-Pathobiology of Disease, Problem Based Learning sessions for second year medical students
-Supervision of pathology resident; gross rounds, frozen sections, sign out and research projects
-Slide teaching sessions for pathology residents

- 2007-present
  - Advanced Clinician Practitioner in Arthritis Care Program, St. Michael's Hospital, University of Toronto, Toronto, Canada

-Bone disease presenting as MSK pain, lectures

- 2003-2005
  - Undergraduate Medical Education, Faculty of Medicine, University of Manitoba, Winnipeg, Canada

-Pathology of Musculoskeletal system, Lectures and practicum sessions for medical students
- Pathology course, practicum sessions for medical students

- 2004- 2005
  - MSc program for pathology assistants, Department of Pathology, University of Manitoba, Winnipeg, Canada

-Microscopic pathology, weekly sessions

- 2004 –2005
  - Postgraduate Education, Faculty of Medicine, University of Manitoba, Winnipeg, Canada

-Pathology of bone, teaching rounds for orthopaedic residents

- 1996-1997 — Tyumen Rehabilitation Centre, Tyumen, Russia
  - Amputee and musculo-skeletal outpatient management Training and supervision of orthopaedic interns

WORKSHOPS

- 2013, November — Correlation Between EUS/FNA of Pancreas and Resection Specimens
  Pathology Update, CME event by the Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Canada
- 2013, May — Difficult Diagnoses in Cytology: Pancreatic FNA, Bile Duct Brushings and Lung EBUS.
  64th Annual Meeting of the Canadian Association of Pathologists 27th World Congress of the World Association of Societies of Pathology and Laboratory Medicine. Quebec City, Canada

MANUSCRIPT PEER REVIEW

- 2012 — Annals of Oncology
- 2013 — Artificial Intelligence in Medicine

PUBLICATIONS

Peer-reviewed

1. A. H. Girgis, **V. V. Iakovlev**, B. Beheshti, J. Bayani, J. A. Squire, A. Bui, M. Mankaruos, Y. Youssef, B. Khalil, H. Khella, M. Pasic and G. M. Yousef Multi-level Whole Genome Analysis Reveals Candidate Biomarkers in Clear Cell Renal Cell Carcinoma. Cancer Research 2012, 72 (20), 5273-5284.

2. Z W Chen, A M Mulligan, P Henry, **V Iakovlev**.
   Mixed Encapsulated Papillary Carcinoma/Invasive Ductal Carcinoma of the Male Breast with Metastasis to Lymph Node. Canadian Journal of Pathology 2012, 4(4) 118-122.

3. M H Chui, C J Streutker, A M Mulligan, **V V Iakovlev**.
   Histological and immunohistochemical features to distinguish between adipocyte hyperplasia, atrophy and neoplasia: differential diagnosis of small round adipocytes in Crohn's disease. Histopathology 2012, 61(5), 984-985

4. **Iakovlev V**, Siegel E, Tsao MS, Haun RS.
   Expression of kallikrein-related peptidase 7 predicts poor prognosis in patients with unresectable pancreatic ductal adenocarcinoma. Cancer Epidemiol Biomarkers Prev. 2012 Jul; 21(7):1135-42.

5. Cawthorn TR, Moreno JC, Dharsee M, Tran-Thanh D, Ackloo S, Zhu PH, Sardana G, Chen J, Kupchak P, Jacks LM, Miller NA, Youngson BJ, **Iakovlev V**, Guidos CJ, Vallis KA, Evans KR, McCready D, Leong WL, Done SJ.
Proteomic Analyses Reveal High Expression of Decorin and Endoplasmin (HSP90B1) Are Associated with Breast Cancer Metastasis and Decreased Survival. PLoS One. 2012;7(2):e30992.

6. N. Arneson, J. Moreno, **V. Iakovlev**, A. Ghazani, K. Warren, D. McCready, I. Jurisica, and S. J. Done.
Comparison of Whole Genome Amplification Methods for Analysis of DNA Extracted from Microdissected Early Breast Lesions in Formalin-Fixed Paraffin-Embedded Tissue, ISRN Oncology, 2012;2012:710692.

7. Dubinski W, Gabril M, **Iakovlev VV**, Scorilas A, Youssef YM, Faragalla H, Kovacs K, Rotondo F, Metias S, Arsanious A, Plotkin A, Girgis AH, Streutker CJ, Yousef GM.
Assessment of the prognostic significance of endoglin (CD105) in clear cell renal cell carcinoma using automated image analysis. Hum Pathol. Epub 2011 Dec 26.

8. **V V Iakovlev**, M Gabril, W Dubinski, A Scorilas, YM Youssef, H Faragalla, K Kovacs, F Rotondo, S Metias, A Arsanious, A Plotkin, AHF Girgis, CJ Streutker, GM Yousef.
Microvascular Density as an Independent Predictor of Clinical Outcome in Renal Cell Carcinoma: an Automated Image Analysis Study. Lab Invest. 2012 Jan;92(1):46-56. doi: 10.1038/labinvest.2011.153. Epub 2011 Oct 31.

9. M Sidiropoulos, A Lausman, M Yudin, **V V Iakovlev**.
Rising Incidence of Syphilis Infection in Canada: A Case Report of Syphilitic Placentitis. Canadian Journal of Pathology 2010 Fall 2:19.

10. C Wang* , **V Iakovlev*** , V Wong , S Leung , K Warren , G Iakovleva , N Arneson , M Pintilie , N Miller , B Youngson , D McCready, S Done.
Genomic analysis of primary breast cancers and their sentinel and distal lymph node metastases: an aCGH study. Genes, Chromosomes & Cancer 2009 Dec;48(12):1091-101.

11. M Pintilie, **V Iakovlev**, A Fyles, D Hedley, M Milosevic, R Hill.
Heterogeneity and power in clinical biomarker studies. Journal of Clinical Oncology 2009 Mar 20;27(9):1517-21.

12. **V V Iakovlev**, N C R Arneson, V Wong, S Leung, G Iakovleva, C Wang, K Warren, M Pintilie, S J Done.
Genomic differences between pure ductal carcinoma in situ of the breast and that associated with invasive disease: a calibrated aCGH study. Clinical Cancer Research. 2008 Jul 15;14(14):4446-54.

13. Pham NA, Schwock J, **Iakovlev V**, Pond GR, Hedley DW, Tsao MS.
Immunohistochemical analysis of changes in signaling pathway activation

downstream of growth factor receptors in pancreatic duct cell carcinogenesis. BMC Cancer. 2008 Feb 6;8(1):43

14. **V Iakovlev**, M Pintilie, A Morrison, A Fyles, R Hill, D Hedley. Effects of distributional heterogeneity on the analysis of tumor hypoxia based on Carbonic Anhydrase IX. Laboratory Investigation, 2007;87:1206-17**

15. C Wang, R Navab, **V Iakovlev**, M-S Tsao, D R McCready, S J Done. Abelson-interactor protein 1 (ABI-1/E3b1) positively regulates breast cancer cell proliferation, migration and invasion. Molecular Cancer Research, 2007;5:1031-9**

16. **V V Iakovlev***, R S Goswami*, J Vecchiarelli, N C R Arneson, S J Done. Quantitative detection of circulating epithelial cells by Q-RT-PCR. Breast Cancer Research and Treatment, 2007;107:145-54

17. N A Pham, A Morrison, J Schwock, S Aviel-Ronen, **V Iakovlev**, M Tsao, J Ho and D Hedley. Quantitative image analysis of immunohistochemical stains using a CMYK color model. Diagnostic Pathology 2007, 2:8(1-10).

*Equal first author contribution
**Figures prepared by the author were used for the front page of the journal issue

Abstracts

1. J. Moreno, R Nair 1, N.A. Miller, B.J. Youngson, **V. Iakovlev**, M. Pintile, D. McCready, S.J. Done.
   DCIS Heterogeneity: An integrated RNA-miRNA analysis. Modern Pathology 2012; 25 Supp: 54A

2. W Dubinski, M Gabril, **V Iakovlev**, Y Youssef, K Kovacs, S Metias, F Rotando, M Moussa, C Streutker, GM Yousef.
   Automated Image Analysis of Endoglin and Microvascular Density in Clear Cell Renal Cell Carcinoma and Its Prognostic Significance. Modern Pathology 2011; 24, 1s: 189A

3. D Tran-Thanh, D-Y Wang, **V Iakovlev**, C Wang, JC Moreno, S Boerner, N Miller, B Youngson, WL Leong, SJ Done.
   Mapping Molecular Alterations in Breast Cancer Using Mammary Ductoscopy. Modern Pathology 2011; 24, 1s: 456A

4. W Dubinski, **V Iakovlev**, M Gabril, Y Youssef, K Kovacs, S Metias, M Mankaruous, GM Yousef.
   Automated Image Analysis of Microvascular Density in Clear Cell Renal Cell Carcinoma and Its Prognostic Utility. Modern Pathology 2010; 23 Supp: 187A

5. H. Faragalla, **V. Iakovlev.**
   Benign symmetric lipomatosis as a late complication to chemotherapy, a case report. 60th Annual Meeting of the Canadian Association of Pathologists, 2009. Pathology - Research and Practice, 2010 206(3): 199 P903.

6. M. Sidiropoulos, A. Lausman, M. Yudin, **V. Iakovlev.**
   Rising incidence of syphilis infection in Canada: a case report of syphilis placentitis. 60th Annual Meeting of the Canadian Association of Pathologists, 2009. Pathology - Research and Practice, 2010 206(3): 210 P955.

7. D Tran-Thanh, **V Iakovlev**, C Wang, V Wong, K Warren, N C Arneson, D McCready, S Boerner, N Miller, B Youngson, W Leong and S J Done.
   Identification of molecular alterations leading to malignancy in ductoscopically procured mammary epithelial cells. 2009 USCAP meeting. Modern Pathology, 2009 22,1S:96A.

8. **Vladimir Iakovlev**, Nona Arneson, Vietty Wong, Chunjie Wang, Stephanie Leung, Gaiane Iakovleva, Keisha Warren, Melania Pintilie, Susan Done
   Genomic alterations associated with the progression to invasive breast cancer revealed by array comparative genomic hybridization. Virchows Archiv, 2008, 452:S1–S286.

9. Melania Pintilie, **Vladimir Iakovlev**, Michael Milosevic, David Hedley, Anthony Fyles, Richard P. Hill.
Heterogeneity and power in clinical marker studies. National Cancer institute proceedings of the meeting Advancing Cancer Research Through Biospecimen Science, 2008, programme.

10. D Tran-Thanh, **V Iakovlev**, C Wang, V Wong, K Warren, N C Arneson, W Leong, D McCready, S Boerner and S J Done
Identification of Molecular Alterations leading to Malignancy in Ductoscopically procured Epithelial Cells. 2008 AACR annual meeting programme.

11. Chunjie Wang, **Vladmir V Iakovlev**, Vietty Wong, Stephanie Leung, Keisha Warren, Gaiane Iakovleva, Nona C R Arneson, Naomi Miller , Bruce Youngson , David R McCready, Susan J Done.
Genomic alterations in primary breast cancers and their sentinel lymph node metastases detected by array CGH. 2008 AACR annual meeting programme.

12. **V V Iakovlev**, A Morrison, R Hill, D Hedley.
A method of assessment of sampling error in biological tissues. 58th Annual Meeting of the Canadian Association of Pathologists, 2007. Pathology - Research and Practice, 2008, 204:53.

13. **V V Iakovlev**, N C Arneson, C Wang, S J Done.
Segments of DNA copy number preferentially altered in invasive breast cancer. 58th Annual Meeting of the Canadian Association of Pathologists, 2007. Pathology - Research and Practice, 2008, 204:31.

14. **V V Iakovlev**, N C Arneson, C Wang, S J Done.
Genomic changes of in situ and invasive breast cancer identified by array comparative genomic hybridization. Proceedings of American Association for Cancer Research annual meeting, 2007.

15. **V Iakovlev**, M Pintilie, A Morrison, A Fyles, R Hill, D Hedley.
The effect of histological tissue sample size on the sampling error. Laboratory Investigation, 2007, 87 Sl:1-350A.

16. **V Iakovlev**, R Goswami, N Arneson, J Vecchiarelli, S J Done.
Quantitative detection of circulating epithelial cells. 57th Annual Meeting of the Canadian Association of Pathologists, 2006. Pathology - Research and Practice, 2006, 202:832.

17. **V Iakovlev**, A Morrison, M Pintile, R Hill, D Hedley.
Quantitative assessment of heterogeneously expressed markers within histological sections. 57th Annual Meeting of the Canadian Association of Pathologists, 2006. Pathology - Research and Practice, 2006, 202:794.

18. Pham N-A, Schwock J, **Iakovlev V**, Ho J, Hedley D, Tsao M-S.
Phospho-protein Immunoprofiling: Activated Signaling Pathways in Pancreatic

Ductal Adenocarcinoma. Pancreatic Cancer 2006: Early Detection and Novel Therapeutics. Conference Proceedings,The Lustgarten Foundation for Pancreatic Cancer Research and AACR, 2006:19.

INVITED SPEAKER

- Sampling error and development of sampling strategies for biological tissues. Fields Institute, University of Toronto, Toronto, September 22, 2006.
  http://www.fields.utoronto.ca/audio/06-07/CMM_seminars/iakovlev/

PRESENTATIONS

- **V Iakovlev,** C Wang , V Wong , S Leung , K Warren , G Iakovleva , N Arneson , M Pintilie , N Miller , B Youngson , D McCready, S Done.
  Genomic analysis of primary breast cancers and their sentinel and distal lymph node metastases. Roderick Ross Research Day, 2008, St. Michael's Hospital, Toronto. Poster presentation.

- **Vladimir Iakovlev**, Nona Arneson, Vietty Wong, Chunjie Wang, Stephanie Leung, Gaiane Iakovleva, Keisha Warren, Melania Pintilie, Susan Done.
  Genomic alterations associated with the progression to invasive breast cancer revealed by array comparative genomic hybridization. Third Intercontinental congress of pathology, 2008, Barcelona, Spain. Oral presentation.

- K Warren, **V V Iakovlev**, N C R Arneson, V Wong, S Leung, G Iakovleva, C Wang, M Pintilie, S J Done.
  Genomic changes associated with duct carcinoma in situ of the breast: an array comparative genomic hybridization study. Canadian Breast Cancer Research Alliance, fifth scientific conference, 2008,Vancouver, Canada. Poster presentation.

- **V V Iakovlev**, A Morrison, R Hill, D Hedley.
  A method of assessment of sampling error in biological tissues. Roderick Ross Research Day, 2007, St. Michael's Hospital, Toronto. Poster presentation.

- S Leung, N C Arneson, V Wong, K Warren, **V V Iakovlev**, S J Done.
  Validation of breast cancer CGH array data using quantitative real-time PCR Summer student program, University of Toronto, Toronto, 2007. Poster presentation.

- **V V Iakovlev,** N C Arneson, C Wang, S J Done.
  Segments of DNA copy number preferentially altered in invasive breast cancer. 58th Annual Meeting of the Canadian Association of Pathologists, 2007. Oral presentation.

- **V V Iakovlev**.
  Identification of DNA copy number changes in invasive and in situ breast carcinoma. Division of Applied Molecular Oncology seminar, Ontario Cancer Institute/Princess Margaret Hospital, Toronto 2007. Oral presentation.

- **V V Iakovlev**, N C Arneson, C Wang, S J Done.
  Genomic changes of in situ and invasive breast cancer identified by array comparative genomic hybridization. Applied Molecular Oncology Division retreat, Ontario Cancer Institute, Toronto, 2007. Poster presentation.

- **V Iakovlev**, R Goswami, N Arneson, J Vecchiarelli, S J Done.
  Quantitative detection of circulating epithelial cells by Q-RT-PCR. University Health Network research day, Toronto, 2006. Poster presentation.

- **V Iakovlev**, A Morrison, M Pintile, R Hill, D Hedley.
  Quantitative assessment of heterogeneously expressed markers within histological sections. 57th Annual Meeting of the Canadian Association of Pathologists, 2006, St. John's, Newfoundland. Oral presentation.

- **V Iakovlev**, R Goswami, N Arneson, J Vecchiarelli, S J Done.
  Quantitative detection of circulating epithelial cells. Applied Molecular Oncology Division retreat, Ontario Cancer Institute, Toronto, 2006. Poster presentation.

- **V Iakovlev**, R Goswami, N Arneson, J, S J Done.
  Detection of circulating epithelial cells by CK19 mRNA. Campbell Family Institute of Breast Cancer Research Annual Retreat,2006, Kimberly, ON. Poster presentation.

- **V V Iakovlev**.
  Analysis of Carbonic Anhydrase IX content within cervical cancer biopsies. Hypoxia Group meeting; 2005, Ontario Cancer Institute, Toronto. Oral presentation.

- **V Iakovlev.**
  LM and EM morphological pattern correlation of malignant spindle cell neoplasms (a pilot study), annual residents research day, 2004; Pathology Department, University of Manitoba, Winnipeg. Oral presentation.

- **V Iakovlev**.
  Comparative analysis of clinical diagnostic discrepancies in the era of declining autopsy rate, annual residents research day, 2003, Pathology Department, University of Manitoba, Winnipeg. Oral presentation.